

WINNING THE RACE TO ELIMINATE HEPATITIS C

Accelerating efforts together to reach the World Health Organization's 2030 elimination targets

BCG

2020

Boston Consulting Group (BCG) partners with leaders in business and society to tackle their most important challenges and capture their greatest opportunities. BCG was the pioneer in business strategy when it was founded in 1963. Today, we help clients with total transformation—inspiring complex change, enabling organizations to grow, building competitive advantage and driving bottom-line impact.

To succeed, organizations must blend digital and human capabilities. Our diverse, global teams bring deep industry and functional expertise and a range of perspectives to spark change. BCG delivers solutions through leading-edge management consulting along with technology and design, corporate and digital ventures—and business purpose. We work in a uniquely collaborative model across the firm and throughout all levels of the client organization, generating results that allow our clients to thrive.

This report has been commissioned and paid for by Gilead Sciences Europe Limited (Gilead). The report was researched and prepared by BCG and reviewed by members of an Advisory Committee.

Local experts were suggested for interview by Gilead. BCG had full editorial control of the final report.

Not all opinions and statements expressed in this report were unanimously supported by all members of the Advisory Committee and, therefore, the text may not reflect the individual opinion of each of its members. The Advisory Committee members express their individual views and not those of the organizations with which they are affiliated.

Contents

- 05** Foreword
- 06** Race to elimination
- 10** Case for elimination
- 14** Where countries stand today and aspiration for the future
- 18** Country strategies based on progress to date
- 24** Elimination strategy depending on populations at risk
- 44** Elimination strategy depending on models of care
- 48** Best practices to accelerate the pace
- 62** Call to action
- 64** Further information



Foreword

Since the publication of Boston Consulting Group's (BCG) report "Road to elimination: barriers and best practices in Hepatitis C management" in 2017, the 29 countries studied in this report have taken various actions towards eliminating the hepatitis C virus (HCV). This included implementing national plans and guidelines, setting up expert groups, eliminating fibrosis-level treatment reimbursement restrictions, and decentralizing HCV testing.

Despite these efforts, little overall progress has been made towards reaching the World Health Organization (WHO) goal to eliminate viral hepatitis as a major public health threat by 2030. Currently, only 10 of the 29 countries considered in the scope of this report are on track to meet the WHO targets, with most countries seeing little real progress since 2017. As such, countries must urgently step up their elimination efforts starting now.

We are very aware of and sensitive to the global health crisis caused by COVID-19, which has undoubtedly made the fight against other diseases more challenging. However, this current crisis should not impede progress in other diseases, especially one such as HCV, which can be eliminated.

We are grateful to BCG for again analyzing HCV elimination and what it will take for countries, indeed the world, to be successful. Importantly, combatting viral hepatitis is included among the United Nations Sustainable Development Goals, and the WHO has set out recommendations to achieve these goals. If countries follow these recommendations, which they committed to in 2014 and again in 2016, and facilitate multi-stakeholder efforts, we are confident that in less than a decade the vast majority of the 71 million people affected by HCV infection will be diagnosed and subsequently cured. We do note, however, that further work will be required beyond 2030 to embed progress and continue the path to full elimination and maybe one day even eradication.

Cary James
Jeffrey V. Lazarus
Andrew Ustianowski



Race to elimination

HCV elimination will not occur without prioritizing this matter, committing the needed resources, and accelerating efforts.

Countries must utilize a variety of initiatives to overcome **multiple obstacles** and achieve elimination.

First, **countries must ensure** that all diagnosed individuals **receive treatment without incurring substantial, or preferably any, costs**. Countries must also establish a **national HCV elimination plan¹ based on reliable, local data²** to guide all domestic elimination efforts.

Second, countries should scale up HCV healthcare strategies by **raising awareness of the disease** and dedicating **more screening resources** to increase the number of diagnosed individuals and prevent new cases.

¹ Hepatitis - Improving the health of patients with viral hepatitis. Sixty-seventh World Health Assembly – A67/13. 28 March 2014.

² Popping, S., et al. The global campaign to eliminate HBV and HCV infection: International Viral Hepatitis Elimination Meeting and core indicators for development towards the 2030 elimination goals. *Journal of Virus Eradication* 2019; 5: 60.

³ Weiner, J., et al. Cost-effective Screening and Treatment of Hepatitis C. *LDI/CHERISH Issue Brief* (2018).

⁴ Holmes, J.A., Rutledge, S.M., Chung, R.T. Direct-acting antiviral treatment for hepatitis C. *The Lancet* 2019; 393: 1392.

⁵ The World Health Organization (2017). *Global hepatitis report*.

⁶ Denmark, England, Germany and Portugal.

Finally, countries must reach marginalized and less accessible patients by **reducing referral times**, **simplifying patient pathways** and ensuring **care is integrated**, coordinated, and decentralized to be closer to patients.

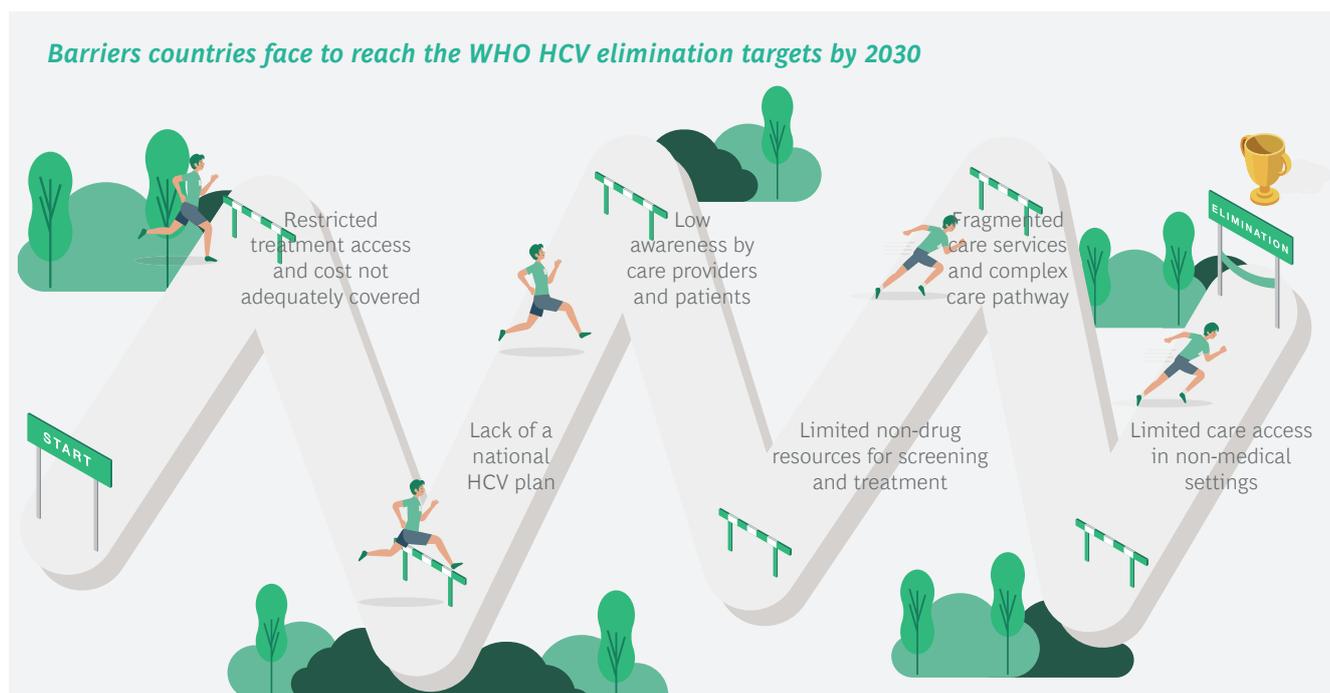


This report identifies several measures to **eliminate viral hepatitis as a major public health threat**

by 2030, a goal established by the WHO in 2016. However, measures may vary depending on the characteristics of each country, namely, their **progress to date**, **populations at risk** (i.e. groups more susceptible to acquiring and transmitting HCV), and **models of care**.

Despite the cost-effectiveness of HCV screening and treatment³ as well as the high rates of sustained virologic response⁴, limited efforts have constrained progress in testing, linkage to care, and treatment for HCV. For example, about 80% of individuals with HCV are still unaware of their condition globally⁵. Further, certain populations at risk still encounter substantial barriers in accessing care.

Just four out of the 11 countries⁶ included in our past report (2017)⁷ have made substantial progress in terms of putting a HCV-specific strategy in place, eliminating treatment restrictions, and achieving improved diagnosis levels. In addition, of the 29 countries within the scope of this report⁸, only 10 are currently on track⁹ to meet the WHO 2030 HCV elimination goal¹⁰. Given that data are not regularly and consistently collected across countries, some discrepancies have been identified across sources regarding which countries are on track to reaching the WHO 2030 elimination goal.



⁷ Australia, Belgium, Denmark, France, Germany, Italy, Portugal, Spain, Switzerland, England and Scotland.

⁸ Australia, Austria, Belgium, Bulgaria, Canada, Czech Republic, Denmark, England, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Romania, Russia, Scotland, Slovakia, Spain, Sweden, Switzerland and Turkey. England and Scotland have been segregated as their HCV elimination programs and government bodies are different.

⁹ Australia, Canada, France, Germany, Iceland, Italy, Spain, Sweden, Switzerland, and the United Kingdom.

¹⁰ Razavi, et al. Global timing of hepatitis C virus elimination in high-income countries: an updated analysis. *Liver International* 2020; 40: 522.

However, we must acknowledge that **countries have made different degrees of progress so far** and will face distinct levels of complexity in their effort to eliminate HCV. The following country archetypes are indicative, and there are also other studies about how countries are progressing towards achieving the WHO elimination targets¹¹.

Elimination strategy approach depending on country archetype



1. Leaders

Focus on less accessible patients

- Simplify patient pathway
- Decentralize care services



2. Followers

Scale up healthcare strategies

- Raise awareness
- Launch screening campaigns



3. Late starters

Improve treatment access

- Eliminate treatment restrictions
- Cover treatment cost

'Leader' countries, which are on track to achieve the WHO targets by 2030, or even earlier, must **focus on reaching the least accessible individuals**.

To facilitate a complete treatment process for this population, they should strongly consider developing diagnosis and linkage-to-care solutions that simplify the care pathway and are located closer to patients' communities.

'Follower' countries can achieve elimination by 2030 but still need to overcome relevant barriers, as many easily accessible patients who have not been diagnosed remain. Therefore, they should **invest dedicated resources to rapidly increase**

diagnosis rates and assess patients for treatment. Thus, key initiatives to establish include scaling-up screening campaigns, increasing knowledge among healthcare providers, and developing awareness campaigns that decrease social isolation, mistrust, and stigma.

'Late-starter' countries need to make radical changes to reach the WHO targets. At the bare minimum, they should consider **focusing on treatment, eliminating restrictions in access** (e.g. provide access regardless of the stage of liver damage, socioeconomic conditions, etc.), and adequately covering treatment costs.

Elimination strategy approach depending on population at risk



PWID

Put effort into linkage to care

- Streamline patient pathway
- Decentralize and integrate care services



MSM

Invest in awareness and prevention

- Create information campaigns to battle stigma and encourage prevention
- Increase screening efforts



Migrants

Expand healthcare access

- Provide free and universal access to the health system
- Raise awareness and offer screening at country arrival



Selected birth cohorts

Focus on diagnosis

- Deploy awareness and screening campaigns
- Reach innovative pricing agreements

¹¹ Palayew A., et al. Do the most heavily burdened countries have the right policies to eliminate viral hepatitis B and C?. *Lancet Gastroenterol Hepatol* 2020.

¹² The World Health Organization (2007). *People-Centred Health Care*.

¹³ Sean B., et al. Where to Treat Uncomplicated HCV? Assessing the Impact of Shifting Care From Specialists to PCPs. *Contagion Live* (2019).

¹⁴ ECDC (2018). *Public health guidance on HIV, hepatitis B and C testing in the EU/EEA: An integrated approach*.

¹⁵ ECDC (2018). *Public health guidance on screening and vaccination for infectious diseases in newly arrived migrants within the EU/EEA*.

However, one size does not fit all. To achieve elimination efficiently, countries must consider their current progress and **adapt their strategy based on two aspects: at-risk groups and models of care.**

Firstly, governments should develop **people-centered programs**¹². These programs must be adjusted depending on the primary sources of infection as well as the demographics and relative size of each population at risk. In this report we will cover four key populations at risk: people who inject drugs (PWID), men who have sex with men (MSM), migrants, and selected birth cohorts.

For **PWID**, the effort should emphasize **linkage to care**. Drop-out rates for this group are particularly high, and some PWID may need extra support to secure an appointment and follow-up with the healthcare professional¹³. Therefore, simplified care pathways and coordinated, decentralized care providers are paramount.

For **MSM**, the resources should be dedicated to **awareness and prevention** by creating educational campaigns to remove HCV-related stigma and encourage preventative behaviors. In addition, establishing screening campaigns adapted to their needs (e.g. developing actions led by peers or making available kits for anonymous at-home testing) and testing for multiple blood-borne diseases (e.g. HCV, hepatitis B (HBV), human immunodeficiency virus (HIV), syphilis) can result in higher cost-effectiveness¹⁴.

For migrants, the focus should be on granting them **healthcare access** in their host countries. Since some migrants do not enter through official immigration channels, they cannot access public health services or lack financial coverage for HCV diagnosis or treatment. Furthermore, this group is hard to track once in the host country, so they should be offered integrated screening (e.g. HCV, HBV, HIV, tuberculosis) shortly upon arrival, followed by linkage

to care, access to treatment, as well as monitoring and evaluation¹⁵.

For **selected birth cohorts** of individuals potentially living with HCV, the key is cost-effectively maximizing **diagnosis** rates¹⁶. Cost pressure intensifies when the country has a low disease prevalence (e.g. Denmark¹⁷). Thus, reaching better pricing agreements with diagnostic and pharmaceutical companies is even more critical for these individuals.

Countries also need to create **models of care** adapted to their local circumstances^{18,19}. The availability of a highly effective and safe oral therapeutic, almost devoid of side-effects, enables the implementation of **simpler** models of care **closer to where patients actually are**.

Models of care also require adequate integration of diagnostic, treatment, and prevention services, ideally in a **'one-stop-shop' approach. A test-and-treat model** is desirable as the model uses simple²⁰, quick diagnostic tests, like dried blood spot testing, and provides results and guidance to start treatment as soon as possible.

To reach more patients and improve the adherence of the most vulnerable populations, like PWID and migrants, countries should aim for **decentralization of services**. It is crucial to move from specialized services at central hospitals and primary care facilities to community centers (e.g. addiction centers, harm reduction centers, prisons, community centers, pharmacies, etc.) and support the availability of **multidisciplinary teams**, including trained medical and non-medical staff and peer support whenever possible.

There is no universal solution for models of care. Countries consider those that best suit their unique health system, epidemiology, and patient populations.

¹² Yartel, A.K., et al. Hepatitis C Virus Testing for Case Identification in Persons Born during 1945-1965: Results from Three Randomized Controlled Trials. *Hepatology* 2017; 67(2): 524.

¹⁷ Christensen, P.B., et al. Hepatitis C prevalence in Denmark - an estimate based on multiple national registers. *BMC Infect Dis.* 2012;12: 178.

¹⁸ Lazarus, J.V., et al. We know DAAs work, so now what? Simplifying models of care to enhance the hepatitis C cascade. *J Intern Med.* 2019; 286: 503.

¹⁹ Bruggmann, P., Litwin, A.H. Models of care for the management of hepatitis C virus among people who inject drugs: one size does not fit all. *Clin Infect Dis.* 2013; 57: S56.

²⁰ Cuadrado, A., Llerena, S., Cobo, C., et al. Microenvironment eradication of hepatitis C: a novel treatment paradigm. *Am J Gastroenterol* 2018; 113: 1639.



Case for elimination

Context

Chronic HCV infection is mostly asymptomatic and can progressively damage the liver over the course of 20 to 30 years with some patients developing irreversible liver damage much earlier. In 2015, an estimated **71 million people had chronic HCV** globally and approximately **399,000 people died** from HCV in 2016²¹, mostly from developing cirrhosis and primary liver cancer (hepatocellular carcinoma).

Before 2014, the available treatment was interferon-based. This had cure rates of around 50%²², multiple side-effects, and restrictions for certain medical conditions, limiting its use in many individuals. Fortunately, all-oral **direct-acting antiviral (DAA) medication** introduced in 2014 has **cure rates**

²¹ The World Health Organization (2016). Available at <https://www.who.int/news-room/fact-sheets/detail/hepatitis-c> [accessed November 15, 2019].

²² Rong, L., Perelson, A.S., Treatment of hepatitis C virus infection with interferon and small molecule direct antivirals: viral kinetics and modeling. *Crit Rev Immunol.* 2010; 30: 131.

²³ Papatheodoridis, G.V., et al. HCV: The beginning of the end—key elements for successful European and national strategies to eliminate HCV in Europe. *J Viral Hepat.* 2018; 25:6.

²⁴ The World Health Organization (2018). Progress Report on Access to Hepatitis c Treatment – Focus on overcoming low and middle countries barriers.

²⁵ Hatzakis, A., et al. Securing sustainable funding for viral hepatitis elimination plans. *Liver International* 2020; 40: 260.

²⁶ Spearman, W., et al. Hepatitis C- *Lancet* 2019; 394: 1451.

over 95%^{23,24}, is well tolerated, and simple to take. This had both a push effect, with more doctors prescribing it, and a pull effect, with more patients willing to receive treatment. Moreover, it has allowed a **change in models of healthcare**. In particular, care management can now be **delocalized** from hospitals and primary care facilities into community settings to better reach high-risk populations.

Treatment access is a key area to focus on, given that some countries still need to remove reimbursement restrictions and adequately cover the costs of the treatment for everyone.

However, the annual **rate of treated individuals living with HCV has dropped** since 2016 as the number of new cases diagnosed has slowed down²⁵. This is because although many countries have expanded HCV treatment coverage, few have nationwide screening programs that can maintain a sufficient number of individuals to treat in the future.

Currently, the main **challenges lie in diagnosis**, driven by a **lack of awareness** of one's status, as HCV is still widely misunderstood and **stigmatized**. It is estimated that globally only 20% of those living with HCV are aware of their status²⁶, and in high-income countries such as the US, this indicator only reaches up to 50%²⁷. As a consequence, there is still a large number of people being diagnosed at a more advanced stage of their infection²⁸ (i.e. people who have >F3 fibrosis stage at the time of diagnosis).

Prevention is also a sensible and **cost-effective solution** that should be prioritized²⁹.

Few countries have advanced significantly during the past few years to a high likelihood of reaching the WHO goal. Most countries have to take immediate action to avoid lagging behind. As 2030 approaches, the need for countries to speed up hepatitis diagnosis and treatment becomes stronger, with many remaining tasks to accelerate efforts towards the elimination goal.

Case for change

There is a clear case for HCV elimination, supported by three main rationales. The first relates to **public health** because without increased investment in testing and treatment of HCV, the virus will continue to spread globally, reaching an estimated **13 million avoidable new cases and 1.1 million preventable deaths by 2030**⁵. The second is purely economic, given the **long-term cost-savings** entailed by investing now³⁰. The third refers to **preventing liver disease progression, morbidity and mortality** for those who live with HCV.

Furthermore, in 2016, the WHO member states unanimously adopted the Global Health Sector Strategy (GHSS), setting the **formal objective of eliminating viral hepatitis (including hepatitis B and C) as a public threat by 2030**. The established targets are³¹:

- 90% reduction in incidence
- 90% of individuals living with HCV diagnosed
- 80% of eligible HCV population treated
- 65% reduction in liver-related deaths

To support these objectives, recommendations on the diagnosis and treatment of HCV aimed at different countries were published²¹. Also, a worldwide movement, “NOhep”³², launched to raise awareness of the disease and pressure national health authorities to commit to elimination. Other initiatives include the “Know hepatitis – Act now” campaign and “World Hepatitis Day”, on the 28th of July, which is an official WHO annual global event.

HCV elimination **requires strong political commitment** to ensure that resources are put in place **through sufficient funding**. It also requires the involvement of all key stakeholders, civil society, the scientific community, hospitals, as well as pharmaceutical and medical companies, which all play an important role in promoting change.

²⁷ Denniston, M.M., et al. Awareness of infection, knowledge of HCV, and medical follow-up among individuals testing positive for HCV: National Health and Nutrition Examination Survey 2001-2008. *Hepatology* 2012; 55: 1652.

²⁸ Mauss, S., Pol, S., Buti, M. et al. Late presentation of chronic viral hepatitis for medical care: a consensus definition. *BMC Med.* 2017; 15: 92.

²⁹ The World Health Organization Europe (2005). What is the evidence for the effectiveness of interventions to reduce hepatitis C infection and the associated morbidity?

³⁰ World Hepatitis Summit 2015 meeting report: Building Momentum, Making the Case.

³¹ The World Health Organization (2016). Global health sector strategy for viral hepatitis 2016–2021. Available at http://apps.who.int/gh/ebwha/pdf_files/WHA69/A69_32-en.pdf [accessed February 20, 2020].

³² Available at <https://www.nohep.org/> [accessed January 20, 2020].

Moreover, there is a need for countries to improve surveillance, monitoring, and **measuring progress towards elimination**³³. Many countries lack reliable epidemiological data, which challenges measuring progress towards specific targets for 2030 and the effectiveness of the healthcare strategies.

³³ Safreed-Harmon, K., et al. The Consensus Hepatitis C Cascade of Care: Standardized Reporting to Monitor Progress Toward Elimination. Clin Infect Dis. 2019; 69: 2218.



Where countries stand today and aspirations for the future

Since our past report was published in 2017, there has been **little progress**, as reflected in the country scorecard (page 15). When comparing the 11³⁴ countries included in the past document, only four (i.e. Denmark, England, Germany and Portugal) have significantly advanced towards the goal of eliminating HCV. The main reason behind this is the lack of effort by national governments.

In 2020, of the 29 countries within the scope of this report⁸ **only 10 are on track**⁹ to meet the WHO 2030 HCV elimination goal¹⁰. These countries have removed treatment restrictions, giving access to all individuals regardless of their degree of liver damage, and have a current treatment rate sufficient to achieve elimination by 2030.

³⁴ Australia, Belgium, Denmark, France, Germany, Italy, Portugal, Spain, Switzerland, England and Scotland.

Assessment of 29 country national plans scorecard

	Plan status and elimination objective			Monitoring and evaluation	
	Strategic plan in place	Year of the latest plan	Eliminate HCV by 2030 (or before)	Monitoring of impact of each of the initiatives	HCV national patient registry
Australia		2018			
Austria					
Belgium					
Bulgaria					
Canada		2019			
Czech Republic					
Denmark					
England					
Finland		2019			
France		2017 plan + Updated recommend. for HBV and HCV (2016)			
Germany		2016			
Greece		2017			
Iceland		2016			
Ireland		2016			
Israel					
Italy		2015			
Luxembourg		2018			
Netherlands		2016			
Norway		2018			
Poland					
Portugal		2019			
Romania		2019			
Russia					
Scotland		2019			
Slovakia					
Spain		2017			
Sweden					
Switzerland					
Turkey		2018			

Yes/Well addressed
 Yes, but no targets/Partially addressed
 Planned
 No/Not addressed
 No plan

1. Sexually Transmitted Infections. 2. Israel Association for the Study of Liver. Source: BCG analysis validated by country experts and clinicians (April 2020).

However, some countries which used to be at the forefront have recently fallen behind. In these settings, a large share of those with HCV remain unidentified and those who are aware of their condition encounter many obstacles to access treatment. There is growing concern that this could also happen to other leading countries³⁵. Comparing where countries were three years ago with where they are currently shows that this effort should be seen as a marathon rather than a sprint.

Currently, around **40% (n=12) of the countries covered by this report still lack a national strategic plan**³⁶, a measure which, in many of the leading countries, has been integral in elimination achievements. Beyond the importance of having such a plan to guide elimination efforts, it also highlights HCV elimination as a public health priority.

In the absence of a national plan, other stakeholders, such as regional bodies, together with private and scientific organizations (e.g. Swiss Hepatitis in Switzerland), have developed **micro-elimination strategies** to provide an alternative solution for those living with HCV. Micro-elimination is a way of moving towards elimination which alleviates the burden of large nationwide elimination efforts through targeting key populations involving multi-stakeholder initiatives and monitoring and evaluation plans³⁷. Although, this approach can create a bias in the scorecard, as some regions within countries might be ahead of the nation as a whole, which is the score reflected in the indicators.

Among those countries with a national plan, only **30% have three or more indicators** regarding the inclusion of the elimination target year (2030 or before) in their plan, adequate monitoring of initiatives, and a national patient registry (indicated as 'Yes/Well addressed' in the country scorecard on page 15). Generally, the initiatives in the plan are **not adequately monitored** due to the difficulties in obtaining reliable data.

In terms of resources, most experts interviewed (see 'Further information' section) highlight inefficient allocation as the main issue hindering progress. Although in most countries DAA treatment is reimbursed without restrictions, additional resources are needed to drive prevention and awareness and to increase the number of people being diagnosed. Having a more integrated system of existing services is key to reach a more efficient allocation of resources.

When looking into the future, leading countries must tackle elimination through a health system perspective and aspire to cover the six core components of the WHO health systems framework: service delivery, health workforce, health information systems, medical procurement, health systems financing, and leadership and governance³⁸. As the components are inherently interdependent, they must be addressed together to support sustainable improvement of the provision of care.

In this report, we acknowledge that accelerating the pace is not easy for countries and each has its own specific circumstances. Thus, we aim to provide a toolbox with which each country can develop its own tailored solution. Therefore, we analyze HCV through three different lenses:

- Countries' progress to date, to learn from others' experiences.
- Populations at risk, to adapt to the specific epidemiology and demography.
- Models of care, to adjust to the available resources and healthcare structure.

Each country should review where it best fits among the three lenses in order to develop a more effective strategy that meets its particular needs.

³⁵ European countries restrict access to life-saving treatment for hepatitis C (2017, April 20). Available at <https://medicalxpress.com/news/2017-04-european-countries-restrict-access-life-saving.html> [accessed April 4, 2020].

³⁶ Refer to the 'Further information' section for the methodology used.

³⁷ Lazarus, J.V., et al. The Micro-Elimination Approach to Eliminating Hepatitis C: Strategic and Operational Considerations. *Semin Liver Dis* 2018; 38(03): 181-192.

³⁸ The World Health Organization (2010). *Monitoring the Building Blocks of Health Systems: a Handbook of Indicators and their Measurement Strategies*.



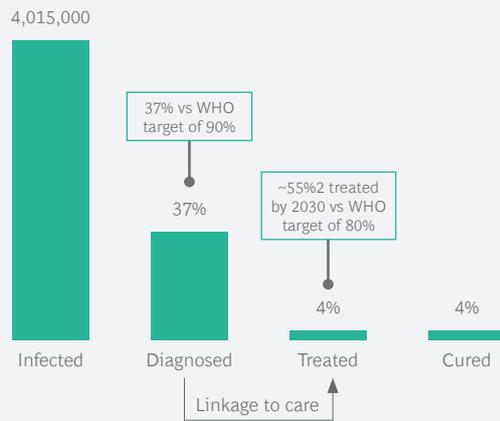
Country strategies based on progress to date

HCV treatment uptake increased rapidly during 2014-15 after the introduction of highly effective DAAs. This was driven by patients who had previously delayed treatment due to the toxicity of earlier drugs³⁹.

Despite the initial surge, treatment rates have been sluggish in recent years. Most policymakers have not promoted large scale measures to increase the number of people living with HCV being diagnosed and treated. Currently, assuming they maintain their current levels of diagnosis and treatment, **76% of high-income countries and territories are not on track** to meet the WHO goal of eliminating HCV by 2030, and 62% are off-track by at least 20 years¹⁰.

³⁹ Mira, J. A., et al. Predictors of severe haematological toxicity secondary to pegylated interferon plus ribavirin treatment in HIV-HCV-coinfected patients. *Antiviral Therapy* 2007; 12: 1225.

Status of care cascade for EU27, UK, Australia & Canada¹



¹Used as a proxy for the report's scope; ²Projecting 2017 annual treatment rate of 4.2% to 2030
Sources: Department of Health of the Australian Government (2018). Fifth National HCV Strategy; George V. Papatheodoridis et al. (2017). HCV: The beginning of the end—key elements for successful European and national strategies to eliminate HCV in Europe; CanHepC(2019). Blueprint To Inform Hepatitis C Elimination Efforts In Canada

When looking at the care cascade, there are still significant gaps. Overall, in the countries analyzed⁴⁰, **less than 40% of individuals with HCV have been tested**, and despite having a backlog of diagnosed individuals, **current treatment rates would be insufficient to reach the WHO targets**, only curing ~55% by 2030 vs the 80% intended. For instance, to achieve the WHO targets, diagnosed cases would need to increase by 7% annually over 2015's baseline, while the number of people treated annually would need to increase by 25% in the next 10 years⁴¹.

Countries must focus on developing different strategies based on their progress to date, the key at-risk groups they need to address, and their models of care.

Country archetypes and key elements to consider for their approach to HCV elimination

Description

Expect to reach WHO targets by 2030 (if not earlier)

Set HCV as one of their main health system priorities



Leaders

Key elements of their approach

Target less accessible patients

- Simplify patient pathway
- Decentralize and integrate care services

Can reach elimination but still need to overcome relevant barriers

Have made progress by eliminating treatment restrictions



Followers

Scale up HCV healthcare strategies

- Raise awareness and battle stigma
- Launch screening campaigns

Need to make radical changes to be able to reach WHO's targets

HCV not acknowledged as a public health priority



Late starters

Focus on treatment access

- Provide free and universal treatment access to all patients
- Develop a national HCV plan

Note: The infographic does not show exclusively the only measures that countries can focus on, rather a pattern of the initiatives that countries that are more advanced in HCV elimination share.

⁴⁰ EU27, UK, Australia and Canada.

⁴¹ Razavi, H., et al. Hepatitis C virus prevalence and level of intervention required to achieve the WHO targets for elimination in the European Union by 2030: a modelling study. *Lancet Gastroenterol Hepatol* 2017; 2: 325.

‘Leader’ countries

Leaders expect to reach the WHO goal by 2030, if not earlier. They have set HCV as one of their top health system priorities, committing substantial resources to leverage the development of DAAs and screening campaigns to eliminate the disease. Thus, they have **high diagnosis rates** and high levels of awareness among physicians.

Nevertheless, they still need to focus on reaching less accessible patients, who are harder to find and to link to care. The most relevant barriers are:

- Complex pathways with long referral times and multiple appointments.
- HCV healthcare services centralized in hospitals, which limits access for high-risk populations and people living in rural areas.

- Lack of sufficient level of coordination among care stakeholders (e.g. hospitals, clinics, prisons, etc.) and low integration within the health system structure.

The overall strategy that leaders are following to overcome the remaining obstacles and reach the most vulnerable patients is based on three pillars⁴²:

- **Pathway shortening**, aiming towards a ‘one-stop test and treat’ for HCV.
- **Decentralization of HCV services**, from large referral hospitals to local level care, enabling care providers to share diagnosis and treatment tasks.
- **Integration of HCV treatment**, including HCV management in primary care and prevention programs.



Specific actions for ‘leader’ countries

1) Shorten pathway

- 1** Use rapid antibody screening and a single reflex viral load test to reduce waiting times
- 2** Promote the use of pan-genotypic DAAs to avoid genotypic testing
- 3** Improve prison inmates’ transfer protocols to outside medical facilities
- 4** Invest in the development of screening technologies (e.g. HCV self-test)

2) Decentralize HCV services

- 5** Allow primary care physicians to diagnose and treat uncomplicated cases of HCV
- 6** Develop innovative solutions such as mobile street units or pop-up clinics
- 7** Provide non-invasive screening toolkits that can be used remotely or in non-specialist settings
- 8** Create specific referral pathways for each patient segment to address their needs

3) Integrate HCV treatment

- 9** Leverage current care structures for other diseases (e.g. HIV, HBV)
- 10** Develop trainings and communication campaigns for healthcare staff
- 11** Use counselling and behavioral therapies to cover other issues that the individual might have
- 12** Create transition programs for inmates still being treated when leaving prison

⁴² AASLD, EASL, APASL, ALEH (2019). Call to Action for Liver Associations to Advance Progress Towards Viral Hepatitis Elimination: A Focus on Simplified Approaches to HCV Testing and Cure.

‘Follower’ countries

These countries can achieve elimination by 2030 but still need to overcome relevant barriers, as many accessible patients who have not yet been diagnosed remain.

So far, they have made progress by eliminating treatment restrictions. These changes have largely been driven by **public pressure** on governments and by a **decrease in drug prices**. In addition, private scientific or patient organizations have proactively promoted the development of guidelines for elimination.

However, most nations have been wary of promoting targeted awareness campaigns, which is also reflected in the current **insufficient diagnosis levels**. This is due to the fear that this would become a large investment in terms of treatment costs and to the stress it could cause to the healthcare network⁴³. For this reason, countries **face a stagnation risk**, as people unaware that they are living with HCV are not being found and linked to care.

The main barriers that hinder progress are:

- Limited non-drug resources (e.g. healthcare workers, medical equipment) to conduct screening and treatment.
- Lack of awareness by care providers and patients.
- Stigmatization of individuals who live with HCV by associating HCV with other stigmatizing issues like drug use and HIV infection.

The overall strategy that ‘follower’ countries should consider developing to step up their game is threefold:

- **Commit necessary amounts of resources** to develop national **screening campaigns** and to absorb new waves of patients.
- **Raise awareness and de-stigmatize HCV** among the targeted population, stressing the importance of **prevention**.
- **Overcome stigma** in healthcare settings.



Specific actions for ‘follower’ countries

1) Commit relevant amounts of resources

- 1** Dedicate specific HCV government budgets, covering treatment expenses and the rest of complementary resources
- 2** Scale up screening strategies adapted to the country’s disease epidemiology
- 3** Reach innovative pricing agreements with pharmaceutical companies and laboratories
- 4** Provide medical equipment and staff to develop testing campaigns within prisons and in community settings

2) Raise awareness and prevention

- 5** Deploy general population awareness campaigns to inform individuals about the virus
- 6** Promote a network-based approach to raise awareness among peers
- 7** Create alert mechanisms to remind healthcare workers to screen individuals who belong to populations at risk
- 8** Inform individuals on protection measures against STIs, and on other measures such as not sharing needles

3) Overcome stigma

- 9** Educate both medical and non-medical staff to fight stigma judgment
- 10** Endorse evidence-based HCV prevention efforts (e.g. harm reduction)
- 11** Include high-risk segments specifically in elimination plans
- 12** Collaborate with cultural and religious organizations to reach specific groups

⁴³ Gountas, I., et al. Economic evaluation of the hepatitis C elimination strategy in Greece in the era of affordable direct-acting antivirals. World J Gastroenterol. 2019; 25: 1327.

‘Late-starter’ countries

These are countries which will have to make radical changes in their strategy to reach the WHO goal. They have not acknowledged HCV elimination as a public health priority, only treating individuals with closer access to the health system or at an advanced stage of the disease.

As a consequence, many marginalized groups are still awaiting treatment and overall treatment rates are very low. The main barriers include:

- Restricted treatment policies, based on factors such as disease stage or drug abstinence.
- Treatment coverage not available to all regardless of their income, hindering access for low-income populations.
- Lack of a national HCV plan to coordinate the elimination strategy.

The overall strategy that late-starter countries must follow to increase their speed and catch up with the more advanced countries in the race to elimination is twofold:

- **Improve treatment access**, offering affordable DAA drugs to all individuals.
- **Increase political commitment**, making HCV a public health priority, and formalized in a publicly available national plan. Ideally, the **plan should be specific to HCV**. However, countries should assess whether a specific plan or an integrated program is more appropriate. (e.g. Canada has included HCV among a wider plan for Sexually Transmitted Infections (STIs)).



Specific actions for ‘late-starter’ countries

1) Improve treatment access

- 1 Promote universal treatment access, regardless of individual characteristics
- 2 Offer full treatment coverage
- 3 Reach agreements with pharmaceutical companies to make drugs more affordable
- 4 Reduce administrative requirements to access treatment (e.g. social security number)

2) Increase political commitment

- 5 Develop a national plan for HCV



Elimination strategy depending on populations at risk

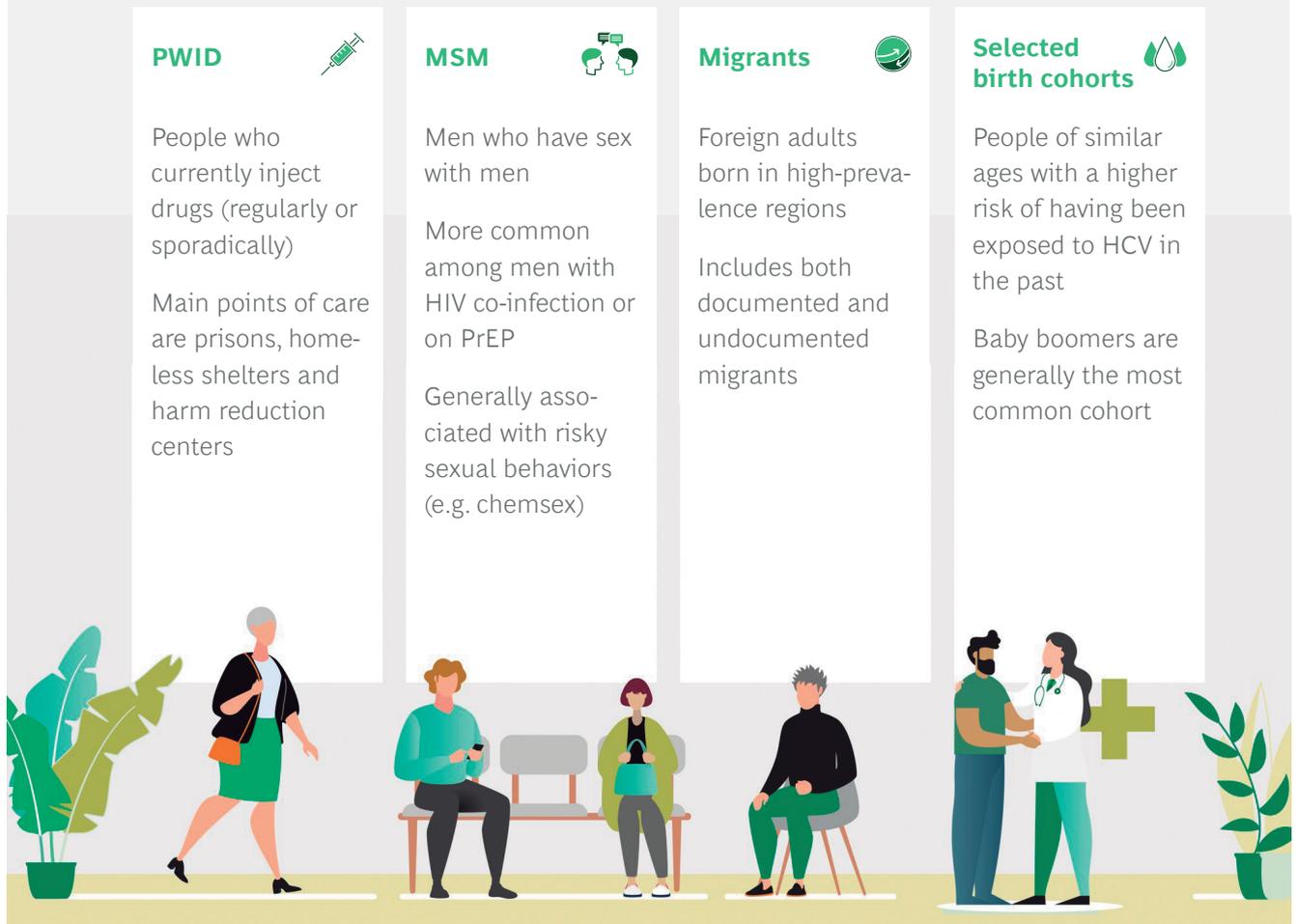
At-risk populations-based strategies enable tailoring the approach to individuals and their specific needs⁴⁴.

Having a strategy targeted at these specific groups allows for a **more efficient use of resources and a person-centered approach**.

This is essential to reach high treatment penetration within these groups and to achieve elimination. Although some people might belong to various groups, approaching them through different routes will ensure that fewer are left behind. Furthermore, some campaign measures are cross-segmental (e.g. increasing general awareness may improve diagnosis rates for every group, as primary care physicians would be more likely to test for the disease).

⁴⁴ Ethgen, O., et al. Public health impact of comprehensive HCV screening and treatment in the French baby-boomer population. *Journal of Medical Economics* 2016, 20: 162.

To achieve elimination, countries should consider the four most relevant populations at risk



Populations at risk have been selected based on **four criteria:**

1. **Higher prevalence** than the overall population's average: 1-2% HCV prevalence (antibody positive) in countries within the scope of this report⁴⁵.
2. **Size:** significant amount of people in the group both living with or without HCV.
3. **Clear screening criteria** for healthcare workers: easily recognizable by workers in order to be tested.
4. **High transmission rates:** a relevant source of new HCV cases.

⁴⁵ Gower, E., et al. Global epidemiology and genotype distribution of the HCV virus infection. J Hepatol. 2014; 61(1 Suppl): S45.

Key highlights of populations at risk



PWID

High

High

Linkage to care

- Simplify the patient pathway
- Decentralize HCV care services
- Integrate HCV in harm reduction programs and primary care



MSM

High

Low

Awareness & Prevention

- Reinforce protection measures and fight stigma with information
- Create common screening campaigns with other blood-borne viruses



Migrants

Medium

Low

Healthcare access

- Provide free and universal access to healthcare services
- Screen individuals upon country arrival



Selected birth cohorts

Low

Medium

Diagnosis

- Deploy targeted awareness campaigns
- Launch cohort screening campaigns
- Reach innovative pricing agreements

In some countries, greater emphasis has been put by the medical community on reaching those groups at higher risk, especially **PWID**, as their prevalence and transmission rates are substantially higher⁴⁶. These individuals can be accessed through specific care models, meaning that screening campaigns can be better targeted. However, **linkage to care** is essential to ensure PWID access to treatment. Thus, pathway simplification, decentralization, and integration of HCV care services must be implemented.

While authorities have focused on reducing HIV among **MSM**, HCV has not had the same level of visibility in many countries. **Prevention measures** and leveraging other STI care platforms as for HIV, will be critical in preventing the virus from spreading further and improving diagnosis rates.

Migrants are the hardest group to track, especially when they are undocumented as limited information exists on this particular population. Furthermore, they form a very heterogeneous group. As such, screening campaigns shortly upon arrival for those born in high prevalence areas offer a good opportunity for identifying new cases of individuals living with HCV. Additionally, free and universal **access to the national healthcare system** is essential to ensure that those diagnosed get treated and can be monitored.

Selected birth cohorts have not been the priority in most countries⁴⁷, despite accounting for a significant share of people living with HCV in some countries. To date, most governments have been doubtful about the cost-effectiveness of awareness and

⁴⁶ Hagan, H., et al. Meta-regression of HCV virus infection in relation to time since onset of illicit drug injection: the influence of time and place. *Am J Epidemiol.* 2008; 168: 1099.

⁴⁷ CDA Foundation (2018). Available at <https://cdafound.org/just-12-countries-worldwide-on-track-to-eliminate-hepatitis-c-infection-by-2030-with-united-kingdom-italy-and-spain-among-those-joining-the-list/> [accessed February 10, 2020].

screening campaigns⁴⁸ and the burden this could put on the health system in the short term. For this reason, reaching innovative pricing agreements with diagnosis and pharmaceutical companies will be paramount to encourage the taking of action in this direction.

People who inject drugs (PWID)

This population comprises of **current injecting drug users**, who mostly take opioids, but also stimulants such as amphetamines or cocaine intravenously. They may inject either regularly or sporadically. The majority of them are men, and prevalence is higher among older people due to risk accumulation over years of potential exposure⁴⁹.

This population has **very high HCV transmission rates**, with some studies suggesting that 20-30% of PWID acquired HCV within the first two years of starting to inject drugs, and 50% within five years⁴⁶. This is partly driven by the strong endurance of the virus, which can live in dry blood on a surface for seven days and inside of a syringe for up to 63 days⁵⁰.

In addition, knowledge of one's HCV status does not seem to decrease the risk behavior associated with injected drugs use⁵¹, and therefore, treatment with DAAs is the best way to prevent transmission in this risk group.

The virus is **generally transmitted through direct sharing of needles and syringes**. For this reason, around two-thirds of the approximately 16 million people who currently inject drugs globally are HCV antibody positive⁵². In developed countries in particular, PWID can represent up to 85% of new cases (e.g. Canada)⁵³.

The size of this group differs widely depending on the country. For example, this group may be prevalent where there have been drug use epidemics (e.g. Canada) or where there is less focus on harm-reduction measures, such as some countries in Eastern Europe (e.g. Slovakia), where only 10% of PWID are able to access needle and syringe programs⁵⁴.

PWID represent a **large share of individuals with HCV in the countries under study**. Moreover, in countries where the HCV epidemic is relatively recent and the majority of those living with HCV were born after 1960 (e.g. Finland, Ireland, or Russia), PWID comprise an even larger percentage.

 PWID	Incidence	Access to new patients	Authorities' focus	Awareness	Cascade challenge	Best practice countries
	High	High	High	High	Linkage to care	

⁴⁸ Helsper, C.W., et al. Effectiveness and cost-effectiveness of nationwide campaigns for awareness and case finding of hepatitis C targeted at people who inject drugs and the general population in the Netherlands. *International Journal of Drug Policy* 2017; 47: 117.

⁴⁹ EMCDDA (2018). *European Drug Report 2018: Trends and Developments*.

⁵⁰ Paintsil, E., et al. Hepatitis C Virus Maintains Infectivity for Weeks After Drying on Inanimate Surfaces at Room Temperature: Implications for Risks of Transmission. *J Infect Dis.* 2014; 209: 1205.

⁵¹ Cox, J., et al. Access to Sterile Injecting Equipment is More Important Than Awareness of HCV Status for Injection Risk Behaviors Among Drug Users. *Subst Use Misuse* 2009; 44: 548.

⁵² Nelson P.K., et al. Global epidemiology of hepatitis B and HCV in people who inject drugs: results of systematic reviews. *Lancet* 2011; 378: 571.

⁵³ Canadian Network on HCV (2019). *Blueprint to inform HCV elimination efforts in Canada*. Available at www.canhepc.ca/en/blueprint/publication [accessed February 20, 2020].

⁵⁴ Eurasian Harm Reduction Network (2013). *Quitting While Not Ahead: The Global Fund's retrenchment and the looming crisis for harm reduction in Eastern Europe and Central Asia*.

Lengthy care pathway, lack of referral protocols, and care concentrated in hospitals are the main barriers

Compared to other at-risk groups, a higher percentage of PWID are aware of living with HCV. However, treatment uptake within this population has historically been very low and non-adherence is also a major obstacle⁵⁵.

The introduction of DAAs reduced treatment-related concerns (e.g. toxicity, ineffectiveness⁵⁶) and improved adherence levels, even among those actively using drugs⁴⁶. However, there are many other psychological, behavioral and social hurdles that jeopardize these patients' pathway to cure.

Additionally, it is essential to bring healthcare closer to PWID in order to address their distinct needs. This can be facilitated through models of care in settings with members of this group, such as prisons, harm reduction centers, and homeless shelters. Those subgroups which are not in contact with any of these models of care pose an even greater challenge to identify and to treat.

The barriers across the care cascade are concentrated around linkage to care but are also present in diagnosis and treatment. The most relevant are:

Awareness and prevention

Mistrust towards institutions due to the fear of stigmatization because of their HCV condition and criminalization of drug use. Past unpleasant experiences with healthcare providers limit this group from attending the conventional care network for medical checks⁵⁷.

Limited access to prevention measures in some selected countries, where there is a reduced number of harm reduction clinics which often have restrictive opening hours, poor quality equipment, and staff with limited knowledge about HCV⁵⁸.

Linkage to care

Lengthy care pathway between screening and treatment, with long referral times and multiple appointments. This means that many patients drop out along the process, especially when the diagnosis requires two visits, one for the antibody screening and another for the confirmatory HCV Ribonucleic Acid (RNA) testing⁵⁹.

Lack of information about the severity of HCV's effects on health, which leads to undesired outcomes, such as diagnosed individuals not considering treatment a priority which leads to unfinished treatments⁶⁰.

Poor medical infrastructure in non-hospital settings such as prisons, harm reduction centers or homeless shelters, lacking qualified healthcare staff to conduct the tests and provide treatment, together with non-medical support personnel and equipment. Therefore, these limitations mean that patients must be referred to medical facilities.

Lack of referral protocols for PWID, who generally require people they trust, such as peers, to guide them throughout the whole process. This support is not straightforward when there are many stakeholders involved, some of which are not familiar with health issues (e.g. prison authorities) or do not perceive HCV as an area within their responsibility (e.g. prison guards and social counsellors). In addition, the existence of multiple budget flows (e.g. funds from a country's health or justice ministries, or private organizations, etc.) add administrative complexity.

⁵⁵ Mason, K., et al. Understanding real-world adherence in the directly acting antiviral era: A prospective evaluation of adherence among people with a history of drug use at a community-based program in Toronto. *Int J Drug Policy*. 2017; 47: 202.

⁵⁶ Mehta, S. H., et al. Limited Uptake of Hepatitis C Treatment among Injection Drug Users. *J Community Health*. 2008; 33: 126.

⁵⁷ Paquette C.E., Syvertsen J.L., Pollini R.A. Stigma at every turn: Health services experiences among people who inject drugs. *Int J Drug Policy* 2018; 57: 104.

⁵⁸ Harm Reduction International (2018): Global State of Harm Reduction.

⁵⁹ World Hepatitis Alliance (2018).

⁶⁰ Zeremski, M., et al. Hepatitis C virus control among persons who inject drugs requires overcoming barriers to care. *World J Gastroenterol*. 2013; 19: 7846.

Treatment

Although a generalized issue, in a few selected countries, treatment restrictions excluding PWID and stigmatization by physicians have a greater expression than in others (e.g. Bulgaria, Slovakia)⁶¹. This severely hinders access to treatment for this group. These policies are based on the belief that these individuals are not deserving of care or that other groups should be a higher public health priority.

Furthermore, for people who cycle often between the prison and community environments and for inmates serving short sentences, there is an additional challenge in accessing care as they may need to deal with many administrative tasks to continue treatment once they leave prison⁶².

Additionally, in some selected countries (e.g. Hungary), there is a heavy administrative burden to access treatment because PWID are highly scrutinized before receiving medication, further complicating the process⁶³.

Additionally, in some selected countries (e.g. Hungary), there is a heavy administrative burden to access treatment because PWID are highly scrutinized before receiving medication, further complicating the process⁶³.

Simplify the pathway, bring care closer to patients, and implement a holistic care solution^{18,64} are the main critical success factors

Since the removal of treatment restrictions in many countries in the last three years, PWID have become one of the highest priority groups for national governments across Europe, Australia, and Canada.

In addition to improving these individuals' quality of life by eliminating the virus, treating this group can serve as an enabler to increase their level of integration into society.

Stimulated by the ease of finding new cases of individuals with HCV, stopping the virus from spreading has been the main priority. Since the prevalence among PWID is much higher than in other groups, they can be located and targeted in specific settings (e.g. prisons, harm reduction centers and homeless shelters).

For this reason, many PWID have been tested for HCV. However, many underestimate the severity of the disease and fail to engage in treatment⁶⁵. Therefore, linkage to care is key. Pathways adapted to the unique needs of PWID are essential.

The critical success factors for this group are:

Awareness and prevention

Develop public campaigns to fight stigma and criminalization of PWID. Moreover, an intense effort must be made to inform physicians about the special needs of the population at risk, highlighting that every individual is deserving of healthcare.

Raise awareness among those affected through programs that inform them about the impact of HCV on their health, the importance of the screening and treatment processes, the relevance of adhering to treatment, potential side effects, chances of cure, and other doubts. In addition, the use of peer-based information campaigns to reduce the distance of PWID from the health system has proven to be an effective measure in many countries to leverage their existing network to reduce mistrust⁶⁶.

Endorse prevention efforts, such as harm reduction programs, which cost-effectively reduce the number of new cases, and can serve as a route of information for individuals with HCV⁶⁷.

⁶¹ Marinho, R.T., Barreira, D.P. Hepatitis C, stigma and cure. *World J Gastroenterol.* 2013; 19: 6703.

⁶² Coalition of Correctional Health Authorities.

American Correctional Association (2015). Hepatitis C in Correctional Settings: Challenges and Opportunities.

⁶³ Falla, A.M., et al. Limited access to hepatitis B/C treatment among vulnerable risk populations: an expert survey in six European countries. *European Journal of Public Health.* 2016; 27: 303.

⁶⁴ Day, E., et al. Hepatitis C elimination among people who inject drugs: Challenges and recommendations for action within a health systems framework. *Liver Int.* 2019; 39: 20.

⁶⁵ Skeer, M.R., et al. 'Hep C's like the common cold': Understanding barriers along the HCV care continuum among young people who inject drugs. *Drug Alcohol Depend.* 2018; 190: 246.

⁶⁶ Crowley, D., et al. Evaluating peer-supported screening as a hepatitis C case-finding model in prisoners. *Harm Reduct J.* 2019; 16: 42.

⁶⁷ Wilson, D.P., et al. The cost-effectiveness of harm reduction. *International Journal of Drug Policy* 2015; 26: 55.

Linkage to care

Simplify the patient pathway aiming towards a 'one-stop test and treat' for HCV. Therefore, health authorities must support the use of:

- Rapid antibody screening and a single reflex viral load test.
- Non-invasive screening tests such as elastography/ FibroScan®. Although not strictly necessary, it can help improve treatment acceptance among these patients.

Bring care closer to patients, by **decentralizing HCV services**, shifting them out of large medical facilities to **include other models of care applied in prisons, harm reduction centers, and homeless shelters**. This can be achieved by:

- Investing more resources in settings where PWID are located, by providing equipment and HCV-educated healthcare staff to support them in the complete testing, linkage to care, and treatment process.
- Allowing primary care physicians and other healthcare workers to diagnose and treat less-complex cases to avoid referral to hospital specialists.
- Developing innovative solutions, such as mobile street units or pop-up clinics, enabled by the use of screening toolkits that can be used remotely (e.g. dried blood spot sampling).

- In the most difficult cases of adherence, promoting counselling and behavioral therapies in combination with opioid substitution therapy (OST), or even with other incentives such as giving money to those who engage in treatment.

Implement a coordinated and holistic care solution for individuals

by creating specific referral protocols which consider the characteristics of PWID models of care. Coordination can be made possible by creating a specific figure accountable for ensuring the whole test and treat process for individuals within each setting. For example, a nurse is assigned to follow up on the patient's progress and coordinate with specialists and healthcare workers within a prison setting. The nurse is also in charge of considering the patient's additional needs such as testing for co-infections or offering additional psychological support.

Treatment

Lift the treatment restrictions in those countries which still maintain them

providing free access to all individuals regardless of their socio-economic status. This should include those currently using drugs or who have acquired HCV again to stop HCV from becoming more widespread in the population (e.g. France treats all those living with HCV with no restrictions).

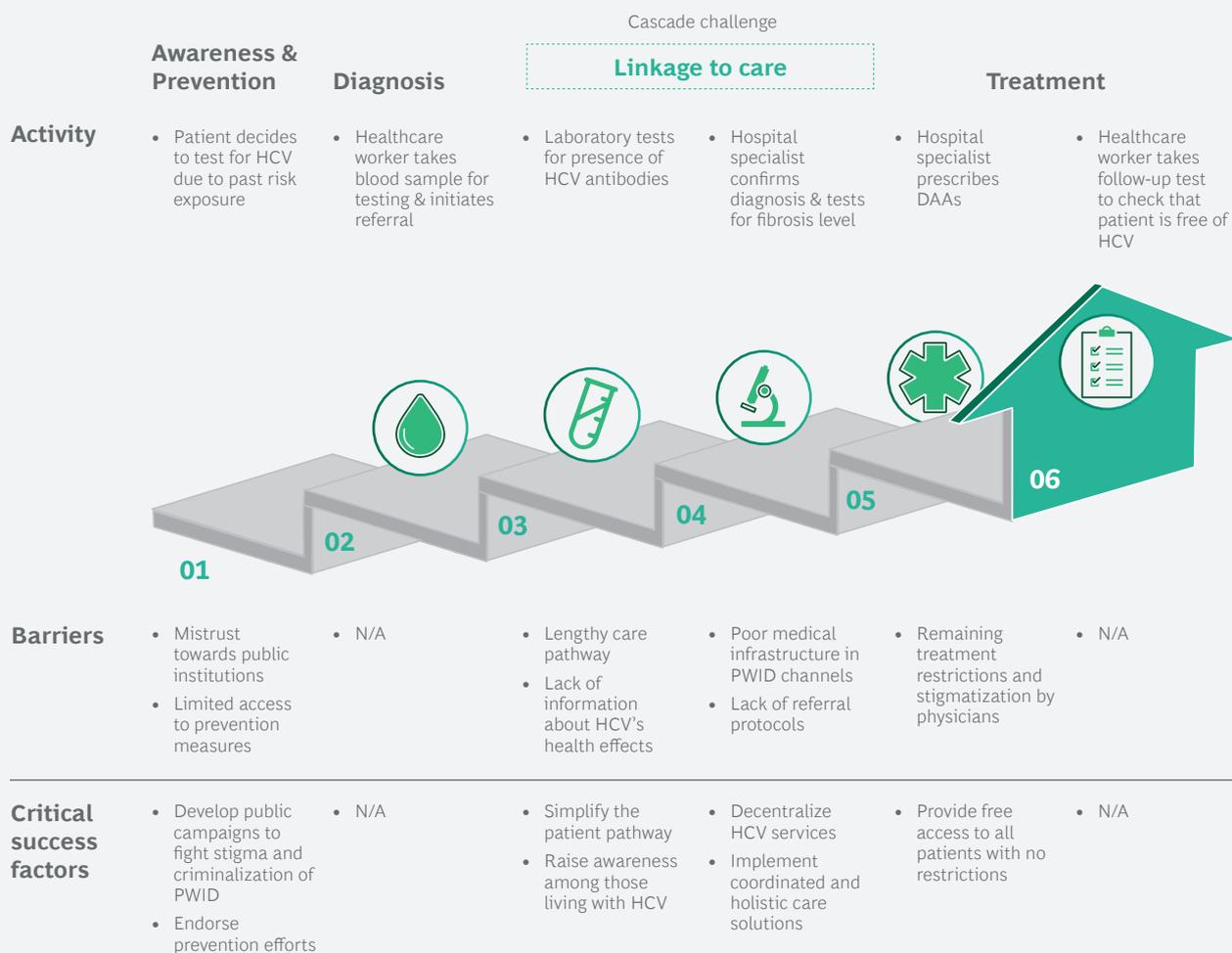
⁶⁴ Day, E., et al. Hepatitis C elimination among people who inject drugs: Challenges and recommendations for action within a health systems framework. *Liver Int.* 2019; 39: 20.

⁶⁵ Skeer, M.R., et al. 'Hep C's like the common cold': Understanding barriers along the HCV care continuum among young people who inject drugs. *Drug Alcohol Depend.* 2018; 190: 246.

⁶⁶ Crowley, D., et al. Evaluating peer-supported screening as a hepatitis C case-finding model in prisoners. *Harm Reduct J.* 2019; 16: 42.

⁶⁷ Wilson, D.P., et al. The cost-effectiveness of harm reduction. *International Journal of Drug Policy* 2015; 26: S5.

Barriers and critical success factors for PWID along the care pathway



Men who have sex with men (MSM)

This refers to men who acquire HCV through unsafe sexual practices with other men. Transmission occurs during condomless anal intercourse where contact with blood may happen or through transmission in semen⁶⁸. In addition, this has been associated with a mix of clinical and behavioral aspects that increase the risk of infection, such as co-infection with HIV or other STIs, men on pre-exposure prophylaxis (PrEP) for HIV, and sexual practices which include drug use (e.g. chemsex).

In the past, **most countries have not considered MSM a priority population**, even though HCV incidence among them has not declined⁶⁹. However, access to care services has been asymmetric. While HIV-positive MSM are more likely to receive routine care and be regularly screened for HCV, HIV-negative MSM have not been targeted by screening campaigns and many remain unaware of their HCV-positive condition⁷⁰.

The lack of awareness around the disease, sexual risk norms within the MSM population, HCV stigma and non-disclosure of HCV status constitute barriers to safer sex, and drug use directly impedes the

⁶⁸ Turner, S.S., et al. Shedding hepatitis C virus in semen of HIV-infected men. *Open Forum Infect Dis.* 2016; 3: ofw057.

⁶⁹ Lockart, I., et al. Sexually transmitted HCV infection: the evolving epidemic in HIV-positive and HIV-negative MSM. *Curr Opin Infect Dis.* 2019; 32: 31.

⁷⁰ Vaux, S., et al. Prevalence of hepatitis C infection, screening and associated factors among men who have sex with men attending gay venues: a cross-sectional survey (PREVAGAY), France, 2015. *BMC Infectious Diseases* 2019; 19: 315.

	Incidence	Access to new patients	Authorities' focus	Awareness	Cascade challenge	Best practice countries
 MSM	High	Medium	Low	Medium	Awareness & Prevention	

self-efficacy of MSM to take risk-reduction measures. This limited awareness is responsible for the **high transmission rates** among the population⁷¹. Also, MSM can sometimes have a higher rate of reinfection than other groups⁷².

However, those few countries that considered this population at risk a priority, for example the Netherlands, where MSM have the highest HCV incidence⁷³, have developed many initiatives focused on increasing awareness of the disease and how to prevent it, together with screening initiatives targeting this particular community. These countries have **leveraged the presence of MSM in HIV-treatment clinics to be able to reach more individuals**. Individuals in these settings benefit from the strong HIV care services network, regular contact with the health system, and high levels of dedicated physicians' attention, as they may suffer faster liver disease progression due to their HIV comorbidity.

Limited information about HCV, false sense of protection, and stigma are the main barriers

Men in this population at risk are not fully aware of HCV and its routes of transmission⁷⁴. Furthermore, they are often guided by the false sense of protection provided by HIV PrEP⁷⁵. Additionally, stigma against individuals living with HCV still remains strong in society at large and among medical practitioners⁷⁶.

Awareness and prevention

Limited information about HCV's effects on health, leading to people underestimating its severity. Most people in the MSM community are highly aware of HIV, as this disease has had a lot of visibility during past decades. Although MSM generally know about the existence of other STIs, such as HCV, they underestimate the impact they can have on their health condition. This lack of knowledge also hinders prevention, with many not knowing about the increased risk attached to sexual practices such as chemsex⁷⁷.

False sense of protection among this community as some measures which protect against HIV, such as PrEP and serosorting (a practice whereby HIV-positive individuals choose HIV-positive sexual partners), are erroneously associated with immunity for all STIs in general⁷⁵.

Diagnosis

Stigma about homosexuality and taboo surrounding sexual behavior, leading to many people not getting tested, and physicians being uncomfortable when asking about potential sexual risk exposures.

Linkage to care

Insufficient healthcare staff to support these individuals throughout the full care process.

In many instances, physicians have very short

⁷¹ Bradshaw, D., et al. Sexually transmitted hepatitis C infection: the new epidemic in MSM?. *Current Opinion in Infectious Diseases* 2019; 26: 66.

⁷² Midgard, H., et al. HCV epidemiology in high-risk groups and the risk of reinfection. *Journal of Hepatology* 2016; 65 J: S33.

⁷³ Grady, B.P., et al. Low incidence of reinfection with the hepatitis C virus following treatment in active drug users in Amsterdam. *Eur J of Gastroenterol Hepatol* 2012; 24: 1302.

⁷⁴ Volansky, R. HCV In MSM: An Epidemic with a 'Shocking' Lack of Education. *Haelio, HCV Next* 2015.

⁷⁵ Traeger, M.W., et al. Effects of Pre-exposure Prophylaxis for the Prevention of Human Immunodeficiency Virus Infection on Sexual Risk Behavior in Men Who Have Sex With Men: A Systematic Review and Meta-analysis. *Clinical Infectious Diseases* 2018; 67: 676.

consultation periods. Therefore, they are not able to dedicate enough time to explain the implications of the virus and link those living with HCV to the care they need⁷⁸. In addition, these individuals might have complex psychological needs linked to their sexual behavior requiring support, which is not always available.

Treatment

Risk of drug interactions with some antiretrovirals for those with co-infection with HIV, needing special attention and adding complexity to linking them to care. Therefore, they might require specialist referrals, which can increase the length of the care pathway.

Limited treatment access based on the risk of reinfection. Homophobic policies or attitudes held by physicians may lead them to withhold care and treatment from MSM in some countries.

Improving information levels, promoting prevention, and increasing testing efforts to reduce incidence and reinfection rates are the main critical success factors

Overall, considering that the men who have sex with men population in some high-income countries is estimated to be around 4% of the adult male population⁷⁹, and that HCV antibody positivity in this group is estimated to be around 4%⁸⁰, they represent a significant share of the population living with HCV, although very few studies have tried to determine the real size of this population at risk.

Health authorities must prioritize this group to prevent transmission. Also, special attention must be given to those with co-infection with HIV, who are at higher risk for disease progression, and reaching them at the early stages of the disease is key to reducing mortality rates.

Awareness and prevention

Reinforce information about protection measures against STIs. HIV PrEP treatment must be preceded by extensive education work on its purpose to eliminate misconceptions.

Diagnosis

Develop public campaigns to fight HCV stigma and homophobia among targeted population and physicians to increase the number of people that are tested. Screening is recommended at least annually for MSM, even for those already treated, or more often if there are multiple risk exposures^{81,82}. To enhance the screening process some initiatives have promoted anonymity, such as **self-testing at home**, while others have been based on **support from community peers** who have had HCV and can help people come forward for diagnosis.

Linkage to care

Leverage the current care structure for HIV and other organizations of the MSM community to screen individuals cost-effectively, inform them about HCV, and provide full care services, including treatment, counselling, and behavioral therapies. However, **high complexity cases** (e.g. co-infections or other comorbidities) will require specialist **referrals**.

Treatment

Eliminate restrictive policies, even in case of reinfection, as scaling treatment in this population at risk is the only way to stop HCV transmission.

In addition, before providing treatment, **inform people of the risks associated with reinfection** and the consequences this can have on the patient's quality of life.

⁷⁶ Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (2012). Stigma and Discrimination around HIV and HCV in Healthcare Settings: Research Report.

⁷⁷ O'Leary, D. The syndemic of AIDS and STDS among MSM. *Linacre Q* 2014; 81: 12.

⁷⁸ Pathela, P., et al. Sexually Transmitted Infection Clinics as Safety Net Providers: Exploring the Role of Categorical Sexually Transmitted Infection Clinics in an Era of Health Care Reform. *Sex Transm Dis*. 2015; 42: 286.

⁷⁹ Purcell, D.W., Johnson C.H., Lansky A., et al. Estimating the population size of men who have sex with men in the United States to obtain HIV and syphilis rates. *Open AIDS J*. 2012; 6: 98.

⁸⁰ Hope, V.D., et al. Prevalence and estimation of hepatitis B and C infections in the WHO European Region: a review of data focusing on the countries outside the European Union and the European Free Trade Association. *Epidemiol Infect*. 2014; 142: 270.

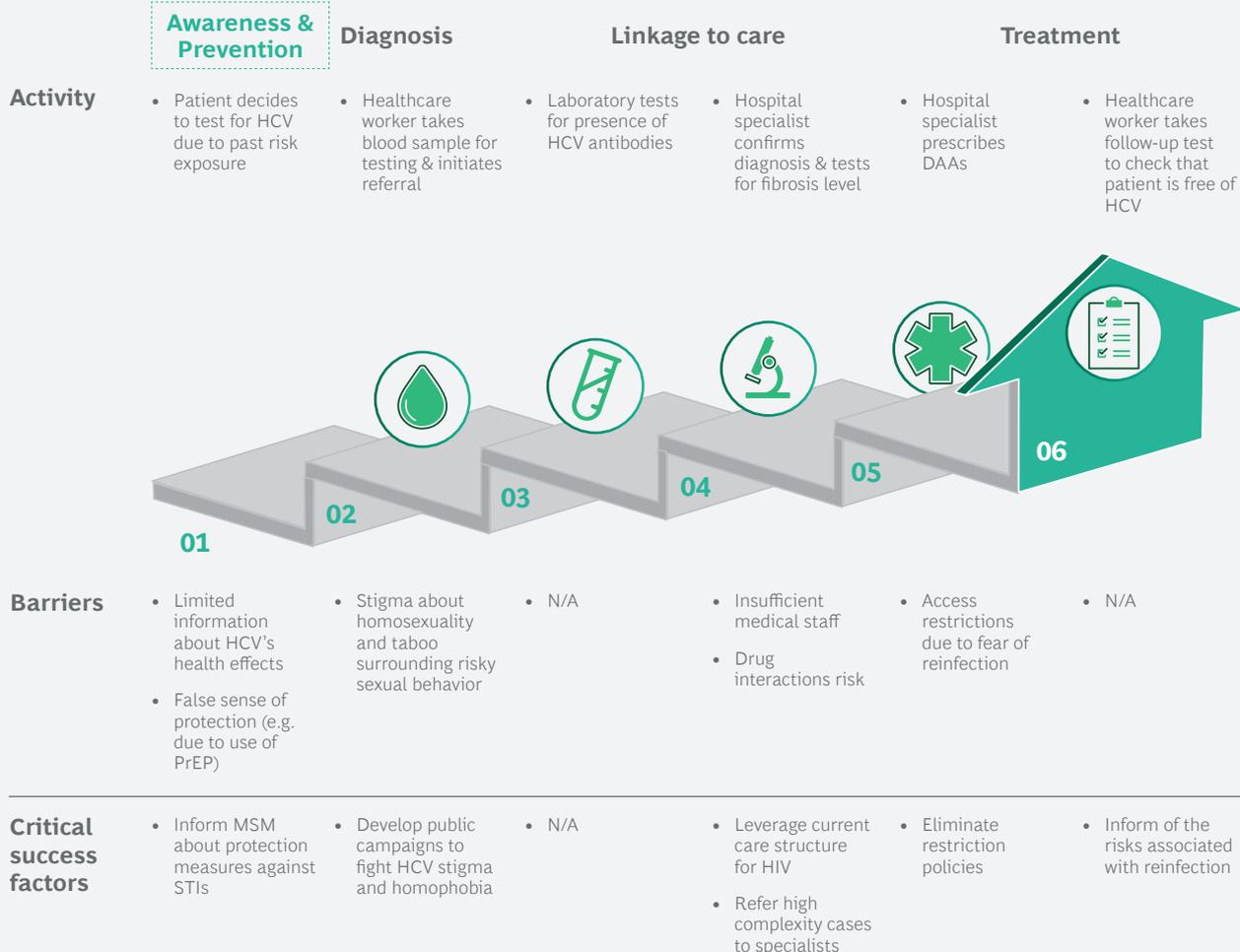
⁸¹ American Association for the Study of Liver Disease and Infectious Diseases Society of America (2019). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C.

⁸² International Union against Sexually Transmitted Infections (2017). European Guideline for the screening, prevention and initial management of hepatitis B & C infections in sexual health settings.

Barriers and critical success factors for MSM along the care pathway

Cascade challenge

Awareness & Prevention



Migrants

This at-risk population includes foreign adults born in high-prevalence countries (Central, Southern and Eastern Asia; Eastern Europe; Middle East and North Sub-Saharan Africa)⁸³ where HCV antibody positivity is around 3-5% vs. 1-2% in countries within the scope of this report⁴⁵, including both documented and undocumented migrants.

They may have acquired HCV via an **array of transmission sources**, the most common being the receipt of contaminated blood products, unsafe injections or medical procedures^{84,85}, resulting from deficient healthcare infection control measures

in the country of origin. Additionally, intravenous drug use, perinatal transmission, or risky sexual practices are also reported as important infection routes. Beyond this, in some cases in their cultural or religious contexts, these individuals may also be exposed to other risk procedures involving reused and unsterilized needles or other sharp objects used in spiritual practices or acupuncture.

Furthermore, HCV rates among migrants are often higher than in their birth countries, suggesting that the **migration process itself may prompt types of behavior that expose migrants to a higher risk of acquiring HCV**, such as exposure to perilous migration journeys that increase the risk of infectious

⁸³ Spradling, P. Hepatitis C. Available at <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/hepatitis-c> [accessed March 12, 2020].

⁸⁴ Pépin, J., et al. Evolution of the global burden of viral infections from unsafe medical injections, 2000–2010. PLoS One 2014; 9: e99677.

⁸⁵ Greenaway, C., et al. The Seroprevalence of HCV Antibodies in Immigrants and Refugees from Intermediate and High Endemic Countries: A Systematic Review and Meta-Analysis. PLoS One 2015; 10: e0141715.

	Incidence	Access to new patients	Authorities' focus	Awareness	Cascade challenge	Best practice countries
 Migrants	Medium	Medium	Low	Low	Healthcare access	

diseases, poor living conditions in host countries (e.g. refugee camps, reception centers, overcrowding or shared accommodation) or limited access to healthcare services⁸⁶.

The size of this population at risk varies greatly among countries as it depends on the size of the foreign-born population and the percentage that come from high HCV-endemic regions (HCV antibody positivity prevalence $\geq 1\%$). For instance, in the EU/EEA approximately 11% of the adult population is foreign-born, 79% of whom were born in endemic countries⁸⁷. In Canada, migrants represent one in three people who are antibody positive but only 21% of the whole population⁸⁸.

Most countries, rather than screening migrants based on country of origin, require the identification of clinical manifestations or risk factors for viral hepatitis (e.g. history of liver disease, HIV or tuberculosis). However results from studies have estimated that screening could be cost-effective if targeted at those born in endemic regions, and some countries have started to apply this broader criterion accordingly⁸⁹.

Stigma, lack of contact with the health system, and limited access to treatment are the main barriers

These individuals have generally not been considered a priority. In fact, only 36.4% of all migrant HCV cases in the EU/EEA were diagnosed, and of these, only 12.7% were treated (2018)¹⁵, and just three EU countries (France, Italy and Ireland), and the UK

along with Australia and Canada, have adopted migrant screening policies¹⁵.

However, in recent years there has been a **movement of large numbers of people from high-prevalence countries to the countries within the scope of this report**⁹⁰, and therefore authorities should consider this group a priority for diagnosis and treatment. **Special attention must be given to undocumented migrants**, as undocumented status decreases their access to the health system while putting them at risk of other serious issues (e.g. homelessness or other infectious diseases of high prevalence in the country of origin). This might lead to delaying seeking healthcare, thus **the postponement of HCV diagnosis and treatment** until advanced stages of the disease.

To target this group more cost-effectively, **authorities must focus on specific models of care in settings such as internment and community centers**, where this community can be more easily accessed.

Although there has been some progress in addressing this group, there are many barriers that lie ahead, especially at a healthcare access level:

Awareness and prevention

Stigma of HCV being a “dirty disease” that migrants bring from their countries of origin⁹⁰, which also makes integration in society more difficult. In addition, there is also censorship within their own community, which prevents individuals from getting tested, or once tested, from starting treatment⁹¹.

⁸⁶ Galli, M., et al. HCV and immigration in Italy. *Acta Bio Med.* 2018; 89: 19.

⁸⁷ Falla, A.M., et al. Estimating the scale of chronic hepatitis C virus infection in the EU/EEA: a focus on migrants from anti-HCV endemic countries. *BMC Infectious Diseases* 2018; 18: 42.

⁸⁸ Tanveer, F., HCV in Canadian immigrants and newcomers: Why are HCV rates higher in these populations? *CATIE* 2017. Available at <https://www.catie.ca/en/pif/spring-2017/hepatitis-c-canadian-immigrants-and-newcomers-why-are-hepatitis-c-rates-higher-these> [accessed February 10, 2020].

⁸⁹ Pottie, K., et al. Evidence-based clinical guidelines for immigrants and refugees. *CMAJ.* 2011; 183: E824.

⁹⁰ Sharma, S., et al. Immigration and viral hepatitis. *Journal of Hepatology* 2015; 63: 515.

⁹¹ Guirgis, M., et al. Barriers faced by migrants in accessing healthcare for viral hepatitis infection. *Internal Medicine Journal* 2012; 42: 491.

Mistrust towards public institutions from those with an undocumented status, fearing deportation or losing custody of their children⁹². This limits their access to standard care networks.

Lack of awareness of frontline workers and primary care providers about the virus and the relevance of addressing this disease because other health conditions, such as acute diseases or psychological afflictions related to the migration process, are considered a priority⁹⁰. Moreover, physicians are not always aware of which regions are HCV-endemic and therefore who should be considered at high risk.

Diagnosis

Lack of resources to test for HCV and staging chronic hepatic disease (e.g. qualified staff or a FibroScan®) in clinics for newcomers and internment centers.

Linkage to care

Language and cultural differences between patients and providers may lead to poor communication and low quality of care.

Nomadic behaviors as individuals with HCV may move through different parts of a city or even across the country in search for a job. These situations hinder the capacity of patients to complete the care pathway.

Limited information, such as medical records or a tax registry, to be able to track them and provide stable care services.

Treatment

Limited access to healthcare services for those undocumented or asylum seekers who are not included in the national health system. This is common in many countries, as undocumented

migrants can only access emergency care services and therefore **cannot access HCV treatment** when the disease is at an early stage. Only some, such as France, have no restrictions whatsoever and all those individuals with HCV are treated.

Administrative requirements (e.g. employment, social security number or permanent residence), therefore excluding indirectly those most vulnerable, or delaying their treatment for long periods of time.

Awareness campaigns, screening policy shortly upon arrival, and access to the health system are the main critical success factors

Driven by **fear of the cost that migrant care could entail for the health system**, many governments limit access to health services, especially as HCV treatment remains expensive. Despite DAA prices being driven down over recent years, most countries have not prioritized this population at risk either in terms of diagnosis or treatment campaigns.

Nevertheless, treating migrants has a threefold benefit, as it can serve to prevent onward transmission of the disease, improve individual quality of life, and facilitate people's integration into society.

The critical success factors for this group are:

Awareness and prevention

Develop public campaigns to battle HCV stigma among this population at risk, collaborating with cultural and religious authorities in order to adapt the campaigns to the specific circumstances of the different subgroups.

Peer-based models which leverage the public image of community influencers (e.g. mosque imams) can also serve to promote awareness.

⁹² EASL position statement on liver disease and migrant health.

Diagnosis

Raise awareness among care providers in order to be able to identify those potentially living with HCV, while reducing stigma towards migrants.

Screening shortly upon country arrival migrants coming from high-prevalence regions is a cost-effective measure, although those diagnosed must be also guaranteed access to treatment.

Linkage to care

Health authorities must work closely with community members and local NGOs to create a greater sense of security for individuals and enhance their linkage to care. In addition, providing

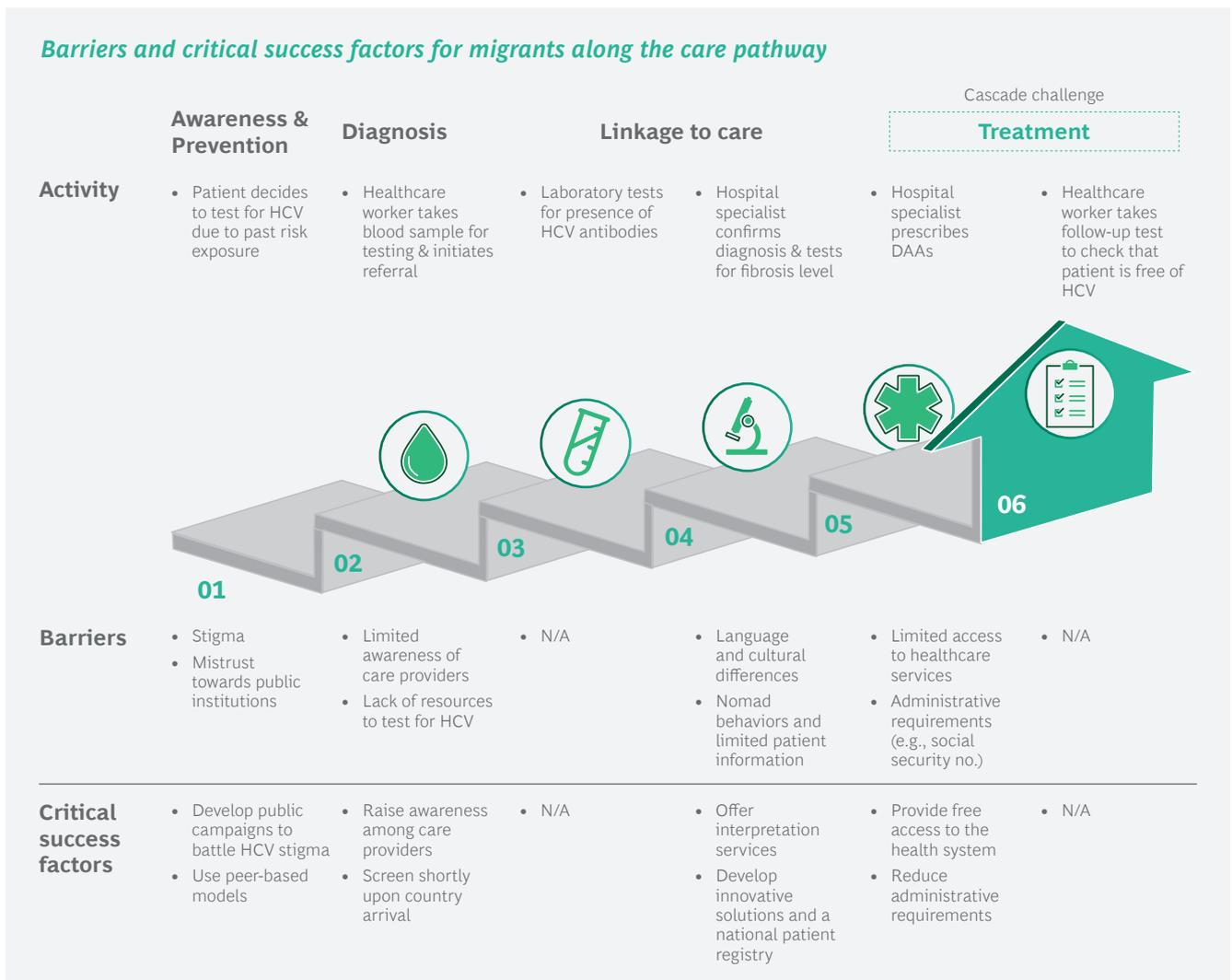
interpretation services could help avoid losing people during the process.

Promote innovative solutions, such as mobile street units that provide care in non-medical locations (e.g. community centers).

National registry to track and assist patients across different regions of the country to ensure as many individuals as possible complete the care process.

Treatment

Provide free access to the health system for migrants, including HCV testing and treatment, **limiting the administrative requirements** as much as possible.



Selected birth cohorts

This refers to groups of people of similar ages who were exposed to a higher risk of acquiring HCV in the past. In many countries, it is a cost-effective screening strategy for targeting particular demographic groups in which there is a higher disease prevalence. Although it depends on local HCV epidemiology, the age groups most commonly considered are people born between 1946 and 1964 (i.e. baby boomers)⁹³.

The reasons why individuals in this group are more at risk of acquiring HCV than other adults are not completely understood, but are thought to be related to:

Blood transfusion with contaminated blood

or blood derivatives before blood screening tests were widely introduced. Blood transfusions were a leading cause of the spread of HCV in most European countries in the past⁹⁴.

This has also been the main cause of infection in North America. In fact, in the US in the 1960s the risk of contracting HCV from a blood transfusion was approximately 33%, while in the 1970s and 1980s, receipt of HCV-contaminated blood products or organs accounted for nearly 50% of new cases of HCV⁹⁵.

The proportion of new HCV cases caused by contaminated blood or organs dramatically declined after the introduction of blood screening tests in the early 1990s.

Contaminated medical equipment or insecure procedures

related to a lack of infection control precautions, such as the use of disposable material or an efficient sterilization of reused equipment in surgery, dental or endoscopic procedures. For instance, in Eastern Europe, HCV healthcare-associated transmission was responsible for 40-70% of cases until the mid 1990s⁹⁵.

Past drug use involving shared needles and other equipment to prepare and inject drugs. This is the main subgroup in Australia⁹⁶ and in many European countries (e.g. Finland, UK), where injection drug use has been the dominant mode of HCV transmission during the past 35 years, accounting for 60% to 90% of prevalent cases²⁹.

Two-thirds of people who have contracted HCV through injecting drug-use no longer inject drugs. Although they share the same infection route as current PWID, they have completely different lifestyles and therefore **need another approach from healthcare providers**⁹⁷.

This group can be divided into two categories based on their awareness or treatment status:

1. **Those who have not been diagnosed** due to the lack of visible symptoms. These individuals need to be identified and screened.
2. **Those who were diagnosed but have not been treated with DAAs.** The reasons behind this are twofold:
 - The diagnosis occurred before the appearance of DAAs in 2014, and the treatment was either postponed, because of its prior toxicity, or was not effective.
 - Additionally, in some countries, treatment is still restricted to those with a certain degree of fibrosis.

⁹³ Who to test HCV Decision-making tables – PICO 2 - www.who.int › hepatitis › publications › annex_4-2, [accessed February 9, 2020].

⁹⁴ Esteban, J., Saucedo, S., Quer, J. The changing epidemiology of hepatitis C virus infection in Europe. *Journal of Hepatology* 2007; 48: 148.

⁹⁵ Alter, H.J., et al. HCV virus and eliminating post-transfusion hepatitis. *Nature Medicine* 2000; 6: 1082.

⁹⁶ Hepatitis Australia (2017). *Reaching Out Report: Strategies for connecting people living with hepatitis C to clinical care.* Part 1.

⁹⁷ Australian Government Department of Health (2018). *Fifth National HCV Strategy 2018-2022.*

 Selected birth cohorts	Incidence	Access to new patients	Authorities' focus	Awareness	Cascade challenge	Best practice countries
	Low	Low	Medium	Low	Diagnosis	  

Lack of awareness of the virus, challenge of promoting testing and cost pressure on the healthcare system are the main barriers

Although this population at risk has good access to the health system network, it is also characterized by low awareness and stigma, which prevent those with HCV from seeking treatment.

The main barriers across the care cascade are:

Awareness and prevention

Lack of awareness about the virus, the risk factors that lead to infection, as well as of the existence of a cure. The individuals with HCV in this group have very little awareness of their condition, as they are a very heterogeneous group and were not targeted in specific public screening campaigns. In fact, in Europe there have been very few specific studies to determine the size of this population and what screening strategies could be more effective. This low attention has been mainly due to their low incidence (e.g. low transmission rate) and to public authorities' fear of overloading the health system due to the size of the group and the associated treatment investment it would require. Lastly, as other more accessible groups are treated, it is also harder to find individuals with HCV among them, levelling the cost-effectiveness.

Stigma has also been a factor holding some doctors back from asking patients difficult questions that may lead to testing, as the disease is often associated to drug use and HIV⁹⁸.

Diagnosis

Challenge of promoting people getting tested, as some are not even aware of having ever been at risk, needing many interventions to encourage them to be screened.

The size of the overall group, both with and without HCV, requires considerable resources to be mobilized for screening. This is exacerbated in the case of countries with low prevalence (e.g. Denmark), in which birth cohort screening is not always cost-effective⁹⁹.

Treatment

Concern of placing **significant cost pressure** on the healthcare system by granting treatment to a significant share of the population.

Nevertheless, **new developments are increasing the cost-effectiveness** of treating these individuals. Firstly, drug treatment costs have decreased considerably¹⁰⁰ in the five years since DAA medicines were introduced. Secondly, there has been an increase in treatment capacity and a reduction in administration costs. HCV has already been integrated within many health systems, together with clear clinical guidelines and simplified process steps.

To increase cost-effectiveness even further, studies show that prevalence varies among different decades of birth depending on the country, so that it is possible to narrow down the selected birth cohorts at higher risk to avoid having to screen everyone in this large group (for example, in the Netherlands

⁹⁸ Treloar, C., Rance, J., Backmund, M. Understanding Barriers to Hepatitis C Virus Care and Stigmatization From a Social Perspective. *Clinical Infectious Diseases* 2013; 57: S51.
⁹⁹ Linas, B., Morgan, J. Literature review on cost-effectiveness of HCV screening, treatment strategies and applicability to LMICs. PICO 2 - Who to test (HCV). Annex 5.2.

most of those with HCV were born between 1950 and 1975, while in Finland they are concentrated after 1960)¹⁰¹. However, epidemiological data is very limited in many countries and would need to be further developed.

In addition, medical staff consider that older individuals are **not worth treating** given the lack of symptoms and low transmissibility.

Launch awareness campaigns, apply targeted cohort screening, and reach innovative pricing agreements to improve diagnosis and treatment rates are the main critical success factors

Policymakers should consider prioritizing this group given that some studies show that they represent 65-80% of adults with HCV in many countries within the scope of this report^{80,102,103}, with an estimated HCV antibody positivity prevalence of ~3%¹⁰⁴. Additionally, as they age, rates of liver failure, liver cancer and death among this birth cohort are expected to rise rapidly, becoming a high cost burden for health systems.

The critical success factors in the care cascade for this group are:

Awareness and prevention

Deploy targeted awareness campaigns to inform individuals about the virus, its consequences and motivate people to step forward for screening.

Educate healthcare staff directly in contact with patients through trainings to fight stigma and better understand the risk factors leading to infection and the severity of its consequences.

Diagnosis

Launch targeted birth cohort screening or pilot other targeting programs. While recommended in the United States¹⁰⁵, general birth cohort screening is not a common practice in most countries. It requires large investments in awareness campaigns and treatment drugs in addition to a healthcare infrastructure capable of withstanding large treatment demand peaks.

However, countries with low prevalence or which cannot commit a significant amount of resources to this effort can learn from this experience by **deploying other targeting strategies** to locate individuals within this group with HCV. Some options are to leverage databases in order to target specific higher prevalence sub-groups of patients within this population or to screen individuals in this cohort who enter an emergency room^{106,107}.

In order to achieve this, **leveraging the connection of the group with the health system** to facilitate large screening strategies is key. In high prevalence countries, this can even be used to promote once-in-a-lifetime screening of the entire population, as this has proven to be an affordable approach in those specific cases¹⁰⁸.

Implement alerts to remind physicians to test individuals potentially living with HCV (e.g. electronic health records used to remind physicians through alerts that a patient who is 50-70+ years old and who has never been screened should be tested)¹⁰⁹.

Treatment

Reach volume-based discounts or innovative pricing agreements, such as a flat-fee model¹¹⁰ (e.g. Australia), to guarantee a steady provision of DAAs.

¹⁰⁰ Pedrana, A., et al. Eliminating Viral Hepatitis. The investment case. Report of the WISH Viral Hepatitis Forum.

¹⁰¹ Gane, E., et al. Strategies to manage HCV virus infection disease burden. *Journal of Viral Hepatitis* 2015; 22: 46.

¹⁰² Lianping, T., et al. HCV testing in Canada: don't leave baby boomers behind. *CMAJ* 2017; 189: E870.

¹⁰³ Brogueira, P., et al. Improve screening of HCV infection by targeting high prevalence aged groups: analysis of a cohort of HCV and HIV co-infected patients. *Journal of the International AIDS Society* 2014, 17: 19601.

¹⁰⁴ Millman, A.J., et al. HCV: Review of the Epidemiology, Clinical Care, and Continued Challenges in the Direct Acting Antiviral Era. *Curr Epidemiol Rep* 2017; 4: 174.

¹⁰⁵ CDC (2012) CDC Now Recommends All Baby Boomers Receive One-Time Hepatitis C Test. Available at <https://www.cdc.gov/nchhstp/newsroom/2012/hcv-testing-recs-pressrelease.html> [accessed April 6, 2020].

¹⁰⁶ Cornett, J.K., et al. Results of a Hepatitis C Virus Screening Program of the 1945–1965 Birth Cohort in a Large Emergency Department in New Jersey. *OFID* (2018).

¹⁰⁷ Hoenigl, M., et al. Universal HIV and Birth Cohort HCV Screening in San Diego Emergency Departments. *Nature Research – Scientific report* 2019; 9: 14479.

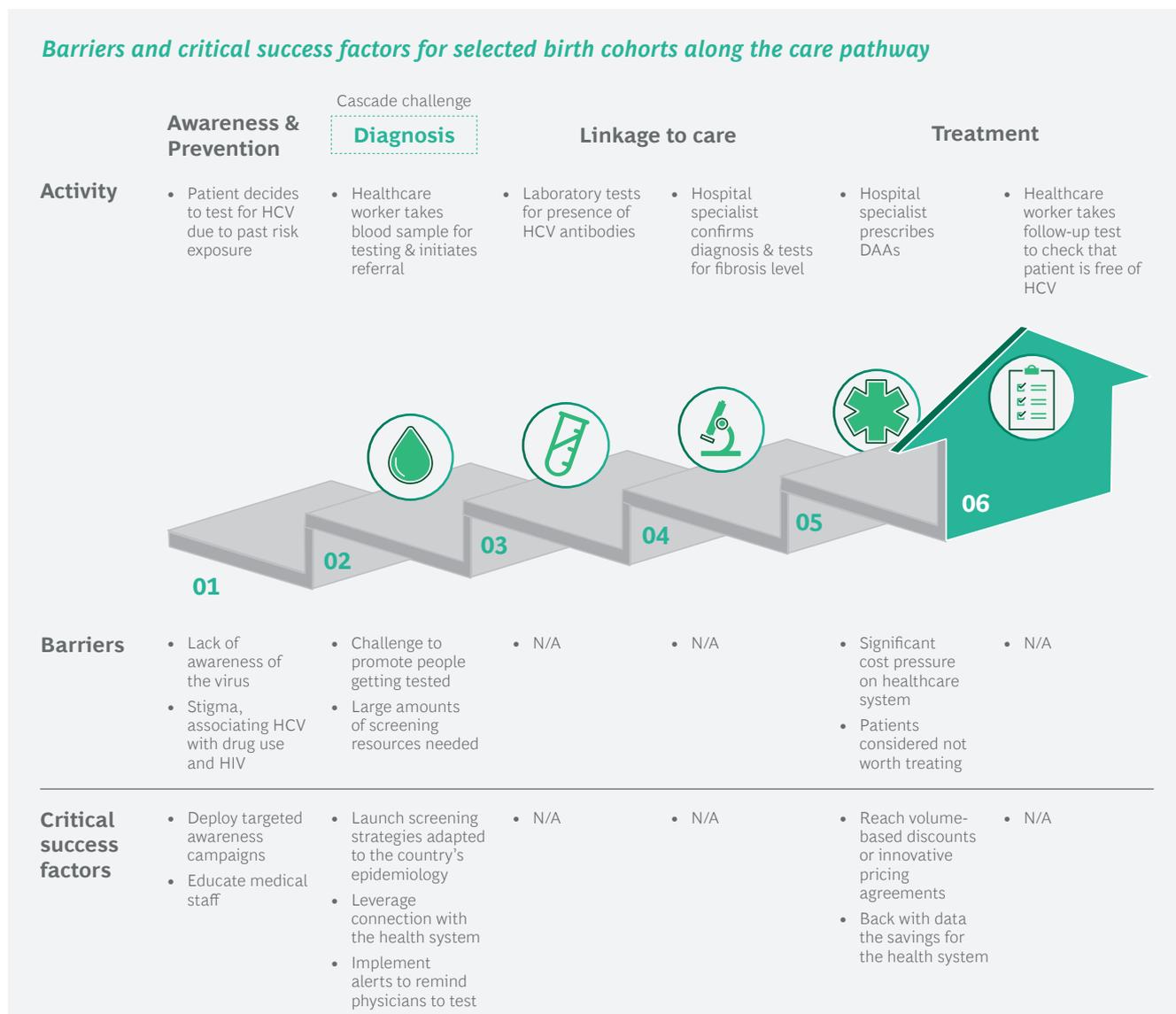
¹⁰⁸ ECDC (2018). Public health guidance on HIV, hepatitis B and C testing in the EU/EEA.

¹⁰⁹ *Infection Control Today* (2017). Electronic Health Record Alert Improves HCV Screening and Treatment Among Baby Boomers.

¹¹⁰ Risk-sharing arrangement with capped annual expenditure but no cap on the number of treated patients.

Use data to provide evidence to support the potential health system savings by treating this group now versus assuming the high cost of having to address liver failure and liver cancer cases in the future, as these individuals age and their health deteriorates rapidly.

Develop clear guidelines ensuring universal treatment in order to formally include these patients as a priority group.



Other groups

Once the main groups are engaged in care and treatment, countries will be close to eliminating the disease. However, in order to eliminate it completely, countries must address the last mile of other populations at risk which are harder to reach.

The patients included in these groups are:

Sex workers: these individuals contract HCV and often transmit the virus to other individuals through risky sexual practices and injection drug use^{111,112}. Sex work is not legal in many settings and sex workers face stigma which may further problematize access to the healthcare system. Some sex workers are concentrated in specific locations, whereas others are geographically dispersed, which makes it more challenging to access them. Oftentimes they can also be irregular migrants who have no access to the health system, which makes it even more difficult to link them to care^{113,114}.

Psychiatric patients: these are individuals affected by mental illnesses (e.g. schizophrenia, depression, bipolar disorder) with high-risk behaviors, often related to past substance abuse or unsafe sexual practices. Due to their condition, they need additional psychological support, and may or may not be located in specific psychiatric centers¹¹⁵.

People located in rural and remote areas: in some countries where the population is dispersed across the territory, it is hard to target those who are located in areas that are more difficult to access, and healthcare and prevention facilities are limited. In particular, those regions not covered by micro-elimination strategies and where a national plan is not expected will have individuals living with HCV whose health condition rapidly deteriorates¹¹⁶.

People who receive tattoos, piercings, and/or manicures in unsafe places: these individuals

have visited specific salons which have particularly low hygiene standards to get a tattoo, piercing, and/or manicure service and thus, could have acquired HCV during the procedure due to the use of contaminated equipment¹¹⁷.

Patients who were treated with DAAs but the treatment was not effective: 5% of those living with HCV who received DAAs treatment and who were not cured after receiving the drug therapy.

Indigenous population: this is a relevant risk population in all countries with indigenous communities (e.g. Australia, Canada and Denmark), as they are more frequently exposed to environments and situations where there is an increased risk of exposure to HCV (e.g. sharing needles, being born to a mother with HCV). They face barriers such as institutional discrimination, which limits access to testing and treatment¹¹⁸.

Children born to a mother with HCV: refers to newborns infected through contact with the blood of a mother living with HCV during labor or via the placenta¹¹⁹.

As prevalence is reduced and individuals with HCV become scarcer, **diagnosis will become increasingly important in order to identify those living with HCV cost-effectively**. Therefore, to address the aforementioned populations at risk, it is essential that authorities focus on finding these individuals through intensive screening programs. In order to make them cost-effective, the following measures can be implemented:

1. **Investing in the development of screening technologies** to reduce testing times, the number of tests, or increase their ease of use (e.g. HCV self-test toolkit).
2. **Simplifying laboratory testing** protocols for HCV to shorten the steps (e.g. reflex testing).

¹¹¹ Goldenberg, S.M., et al. Dual sexual and drug-related predictors of hepatitis C incidence among sex workers in a Canadian setting: gaps and opportunities for scale-up of hepatitis C virus prevention, treatment, and care. *International Journal of Infectious Diseases* 2017; 55: 31.

¹¹² Shafraan, S.D. Hepatitis C and the sex trade. *Can J Gastroenterol Hepatol.* 2015; 29: 405.

¹¹³ Rekart, M.L. Caring for sex workers. *BMJ* 2015; 351: h4011.

¹¹⁴ Soclas, M.E., et al. Comment on (Hepatitis C and the Sex Trade). *Canadian Journal of Gastroenterology and Hepatology* 2016, Article ID 1253208.

¹¹⁵ Rado, J. Hepatitis C among the mentally ill: Review and treatment update. *Current Psychiatry* 2017; 16: 41.

¹¹⁶ Cheng, W., Nazareth, S., Flexman, J.P. Statewide hepatitis C model of care for rural and remote regions. *J Gastroenterol Hepatol.* 2015; Suppl 2:1.

¹¹⁷ Hwang, L.Y., et al. CDC Study on HCV Risk Transmission & Tattoos/Body Piercing, Snorting Drugs: Relationship of cosmetic procedures and drug use to hepatitis C and hepatitis B virus infections in a low-risk population. *Hepatology* 2006; 44: 34.

¹¹⁸ Bruce, V., et al. Hepatitis C Virus Infection in Indigenous Populations in the United States and Canada. *Epidemiologic Reviews* 2019; mxz015.

¹¹⁹ Yeung C.Y., et al. Vertical transmission of hepatitis C virus: Current knowledge and perspectives. *World J Hepatol.* 2014; 6: 643.

3. **Avoiding retesting through monitoring systems** to be able to follow up with those already diagnosed or recently tested as negative for infection. These individuals would be those who have already been tested and have not exposed themselves to risky behavior, those who experienced ineffective treatment, and children who are too young and therefore cannot be treated yet.
 4. **Sharing costs** with other blood-borne or sexual contact-transmitted diseases (e.g. HIV, HBV, syphilis) by combining their tests.
 5. **Optimizing the targeting of individuals living with HCV through the use of big data and artificial intelligence**, being able to identify high-prevalence sub-groups more successfully.
- Increased investment in needle exchange programs, drug consuming rooms and condom distribution.
 - Increased network of harm reduction centers making new syringes accessible to PWID.
 - Increased awareness among people with multiple partners and involved in risky sexual practices of the importance of proper condom use in preventing multiple STIs.

Special focus should be put on young people because, although most will not show symptoms for many years, they are exposed to many kinds of high-risk behavior and therefore transmission rates may be higher^{123,124}.

Success in reaching these patients will only be achieved by investing effort in making **screening more accessible and targeted** towards these specific micro-groups.

Moreover, the absence of an HCV vaccine makes early diagnosis and treatment the best tool to prevent HCV from spreading again and avoid losing the ground already gained.

Besides this, **primary prevention measures** are cost-effective means of preventing new cases. We highlight the following, most of them already covered in previous chapters^{120,121,122}:

- Screening and testing of blood, plasma, organ, tissue, and semen donors.
- Virus inactivation of plasma-derived products.
- Implementation and maintenance of infection-control practices in healthcare services.
- Increased regulation and surveillance of centers of cosmetic procedures like tattooing, body piercing, barbering or manicure for proper infection-control practices.

¹²⁰ CDC (2016). Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease.

¹²¹ Shalmani, H. M., et al. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. *J Liver* 2013; 3: 2.

¹²² Advisory Council on the Misuse of Drugs (2009). The primary prevention of Hepatitis c among injecting drug users.

¹²³ Giraudon, I., et al. Hepatitis C virus infection among people who inject drugs: epidemiology and coverage of prevention measures in Europe. *EMCDDA Insights* 23. 2016: 21.

¹²⁴ Wolfers, M., et al. Adolescents underestimate risk for STI and deny the need for STI testing. *AIDS Patient Care and STDs* 2010; 25: 311.



Elimination strategy depending on models of care

Since a large proportion of people living with HCV are not currently accessing treatment, there is an urgent need to **reshape the entire cascade of care**, according to specific population needs.

Models of care outline how to provide the relevant services and interventions during the different stages of the individual's care pathway, including testing, linkage to care, retention in care, treatment, chronic care, and prevention of primary infection and reinfection. Decisions on what strategies to adopt to improve the performance of each country will depend on the local epidemiology of the disease, the social context, and healthcare system conditions^{18,100}.

The conventional paths of managing individuals living with HCV are associated with a set of barriers. One of the major obstacles is the lack of treatment settings adapted to the special needs of at-risk groups (e.g. PWID, migrants), still having to improve issues such as stigma and discrimination, high cost of care, distance from care sites, transportation costs, or long waiting times at the facility¹²⁵. Furthermore, a lack of HCV knowledge in primary care units, harm reduction centers, and shelter centers, among others, prevents these institutions from providing treatment¹⁹.

A successful model of care must have the following hallmarks^{18,97,100}.

Simplicity, scalability and patient convenience

Because DAAs are highly effective, have few side effects, and can be administered orally, it is possible to design much simpler models of care. Other elements that contribute to simplicity include integration of services and bringing healthcare closer to the places where patients are.

Test and treat model

The application of a test and treat model is highly recommended, wherever possible, to eliminate gaps between diagnosis and treatment.

On-site single sampling episode with rapid results, a pre-test discussion and education, demonstrated to be effective in increasing HCV screening. Moreover, **simple and quick diagnostic methodologies must be preferred**. Some good examples are the use of dried blood spot testing, where it is also possible to apply reflex testing¹²⁶, and the use of transient elastography (that can be a portable piece of equipment) or biochemical scores, like aspartate transaminase to platelet ratio index (APRI), to evaluate the level of fibrosis.

Enabling policy environment

This is a very important point to address the most vulnerable people, like PWID, migrants, or homeless people. Restrictive policies, such as the criminalization of drug use, preclude these patients from accessing healthcare services, including community support services, and contribute to increasing the stigma among the general population.

A **high level of acceptance of individual life circumstances**, rather than rigid exclusion criteria in selecting patients for treatment (e.g. based on active drug or alcohol consumption), will determine the success of HCV elimination.

Affordability and availability

Referring primarily to diagnostic tools and treatment, so that no affected populations are left behind for any reasons. This implies, for example, access to free treatment or providing assistance with transport if the treatment center is far from the testing site.

At a country level, there are some measures that can contribute to better financial resource management:

Formulating national testing and treatment guidelines that specify which medicines and diagnostic assays should be used.

Determining whether generic medicines are available in the country, if DAAs are not protected by a patent or if the country is included in the respective license agreement.

Registration and inclusion in the national essential medicines list, as registration of products from as many manufacturers as possible will increase competition and lower prices.

Estimating the volume of products required to meet program demand, according to the number of people waiting for treatment and the expected rate of scale up for testing and treatment activities.

¹²⁵ The World Health Organization (2018). Guidelines for the Care and treatment of persons diagnosed with Chronic Hepatitis c virus Infection.

¹²⁶ Application of a molecular biology test for ARN-VHC detection after a positive antibody screening test.

Enhancing procurement activities either through **price bidding** (generic medicines) or **economies of scale** (original drug makers).

Multidisciplinary delivery of care

The delivery of care should encompass medical and non-medical professionals in the core team (doctors, nurses, psychologists, social workers), including peer support whenever possible, and/or professionals trained to provide multiple services for biomedical, psychoeducational, and social coverage of the individual. Peer-led interventions can be particularly effective in reducing stigma, improving the acceptability of services and treatment compliance, and making the global integration of the most vulnerable patients into the care cascade easier¹²⁷.

Integration of services

It is key to bring services closer to the patient, rather than expecting the patient to seek them out.

There are three types of potential service integration:

Providing testing for HCV in different settings, reducing duplication of services and improving coordination (e.g. services/clinics that manage other diseases with the same risk factors, like HIV, HBV, STI; or those aimed at the same risk groups, like PWID, migrants, MSM, incarcerated people, sex workers, psychiatric patients, etc.).

Integrating the diagnosis of HCV with diagnostic platforms and laboratory services used for other infections, such as using the same blood sample to screen for different diseases such as HBV, HIV or syphilis. This provides significant system efficiency and cost savings¹⁰⁰.

Combining service delivery of care, prevention and treatment, as the continuity between prevention and care is needed to ensure ongoing

harm reduction measures and avoid individuals acquiring HCV again, especially among PWID and MSM.

Decentralization of services

Care services should be delivered at peripheral health facilities, community-based venues, and locations beyond hospital sites, **bringing care closer to where patients are**. This may reduce transportation costs and waiting time for a specialized consultation, amplify care, and capture patient compliance.

This will require simple and portable diagnostic means as mentioned above, good referral networks, and robust computer systems that prevent the dispersion and loss of clinical information. It will be facilitated by simple treatment algorithms, with access to regimens that are effective against every genotype.

There are already some successful approaches in operation, mainly aimed at clinically well and stable patients, using **mobile units** with multidisciplinary teams or professionals with multiple skills, **telemedicine, nurse-led**^{128,129}, or **pharmacist-led programs**¹³⁰. This task-sharing with non-specialists, nurses or other professionals requires provision of appropriate training and easy access to additional support or referral to a specialized service of complex cases.

The delivery of HCV services and interventions varies tremendously in practice, and the settings where they can be offered depend on the structure of the healthcare system of each country. Beyond the specialized centers at central hospitals and primary care facilities, there are multiple successful examples of implementing the HCV care cascade in community health centers, addiction centers and harm reduction centers, prisons, pharmacies, or sexual health clinics¹⁸.

¹²⁷ Surey, J., et al. From peer-based to peer-led: redefining the role of peers across the hepatitis C care pathway. HepCare Europe. Journal of Antimicrobial Chemotherapy 2019; 74: v17.

¹²⁸ Papaluca, T., et al. Outcomes of treatment for hepatitis C in prisoners using a nurse-led, statewide model of care. J Hepatol. 2019; 70: 839.

¹²⁹ Overton, K., et al. Outcomes of a nurse-led model of care for hepatitis C assessment and treatment with direct-acting antivirals in the custodial setting. Int J Drug Policy 2019; 72: 123.

¹³⁰ Koren, D. E., et al. Expanding Hepatitis C Virus Care and Cure: National Experience Using a Clinical Pharmacist-Driven Model. Open Forum Infect Dis. 2019; 6: ofz316.

Data systems

These are key to monitor the quality and suitability of the different models of care. The WHO suggests three indicators to evaluate the HCV cascade of care: (1) the proportion of people with HCV diagnosed; (2) treatment initiation rate; and (3) the proportion of those treated who are cured.

Not all models are feasible for every healthcare system and no model meets the needs of every single patient. Therefore, it is important to have a variety of different models and approaches available.



Best practices to accelerate the pace

Best practices have been identified in all countries in scope. However, we have made a short selection of 12 case studies from various countries that have implemented innovative strategies to eliminate HCV. The strategies illustrate how countries have been successful at implementing initiatives adapted to the progress made so far and how they have addressed specific populations at risk and models of care.

Country best practices scope at a glance

MoC	PWID		MSM		Migrants		Birth cohorts vs. Other groups	
Hospitals							✓	✓
Primary care							✓	✓
Community health centers	✓		✓	✓	✓		✓	
Pharmacies	✓							
Harm reduction centers	✓	✓						
Prisons		✓	✓					
Homeless shelters	✓							
Sexual health clinics				✓				
Internment centers						✓		
Other	✓			✓		✓	✓	✓



Kombi Clinic (Australia)



Caserta model (Italy)



Care in prisons (Spain)



Latino MSM prevention (Canada)



Home-based testing (Netherlands)



Integrated screening (Portugal)



Integrated care for refugees (Australia)



Arrival care services (Italy)



Foreign-born screening (Scotland)



C-Free-South (Denmark)



Tour de France (France)



Focus Galicia (Spain)

KOMBI CLINIC OUTREACH MODEL OF PCP CARE

POPULATION AT RISK



PWID

LOCATION



Brisbane, Australia

Authors: Joss O'Loan, Matt Young and Mim O'Flynn



PURPOSE

Take free HCV screening and linkage to care to the streets

WHY IS THE MODEL NEEDED?

- Long hospital waiting times
- Fear of blood tests and treatment side effects
- Fear of stigma
- Lack of access to non-invasive screening tests
- Lack of knowledge by physicians and patients about DAAs
- Limited medical access in rural areas

WHAT IS THE MODEL ABOUT?

All-inclusive PCP-led mobile hepatitis clinic in a 1975 VW Kombi van



Location

Drug, alcohol and mental health services, homeless shelters and other community centers



Resources

2 1 1

PCPs Nurse Phlebotomist

HOW DOES IT WORK?

Visit 1 <20 mins

- I. Patients speak to a PCP
- II. FibroScan®
- III. Whole blood draw via venesection
(sent for testing and returned after ~3 weeks)

Return to same venue 4 weeks later



Visit 2 <20 mins

- I. Test results reviewed
- II. Treatment prescribed
- III. Follow-up visits arranged

Patient collects prescription at local pharmacy – \$20 supermarket voucher provided

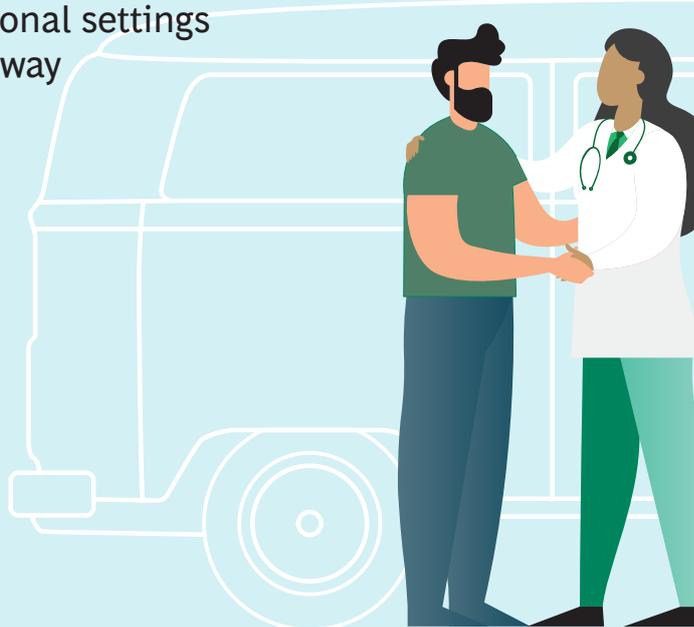
OUTCOME: THE KOMBI CLINIC IN 2019

Achieved cure rates similar to 'standard' models of care in non-traditional settings by simplifying patients' pathway

914
individuals
screened

216
patients
diagnosed

66%
started
treatment



CASERTA MODEL OF INTEGRATED HCV CARE

Authors: Vincenzo Messina, Filomena Simeone, Angela Salzillo and Nicola Coppola

POPULATION AT RISK



PWID

LOCATION



Caserta, Italy



PURPOSE

Simplify the HCV patient journey to improve linkage to care for PWID

WHY IS THE MODEL NEEDED?

- Lack of screening at PWID channels
- Long waiting list for specialist referral
- Multiple hospital visits
- Limited equipment due to lack of resources
- DAAs prescribed only at specialist centres

WHAT IS THE MODEL ABOUT?

Integrated and simplified model of care between hospitals and PWID channels



Location

Harm reduction centers and prisons



Resources

1

Nurse

1

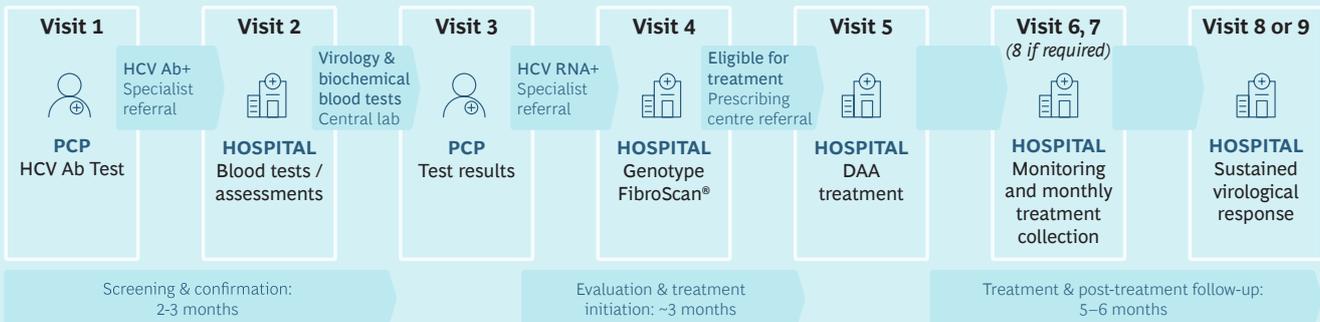
Doctor

1

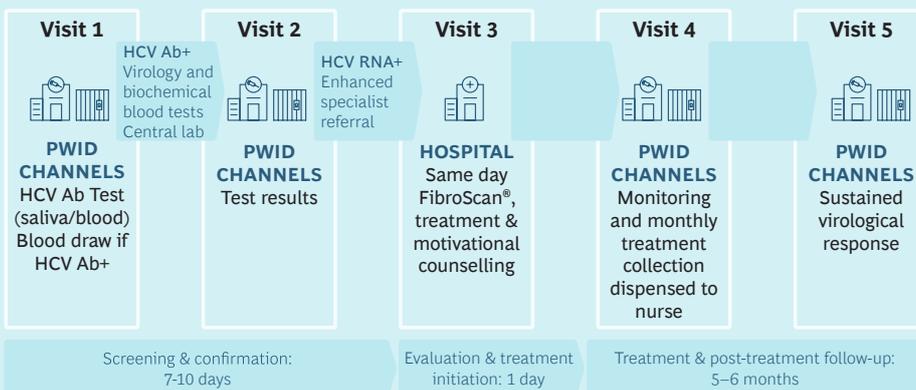
Hepatologist

HOW DOES IT WORK?

Standard of Care



Simplified Pathway



OUTCOME: THE CASERTA MODEL IN 2019

Reduced drop-outs for high-risk populations by shortening their care pathway

~50%

shorter lead time to cure patients

410

individuals screened

85

patients cured



HCV CARE MODEL IN PRISONS

Authors: Andres Marco Mourio, Joan Colom Farran and Neus Solé i Zapata

POPULATION AT RISK



PWID

LOCATION



Catalonia, Spain



PURPOSE

Eliminate HCV in the inmate population through a coordinated response of all involved stakeholders

WHY IS THE MODEL NEEDED?

- Poor medical infrastructure in non-hospital settings
- Lack of referral protocols
- Administrative bottlenecks
- Discoordination among stakeholders
- Multiple medical appointments
- Limited capacity to follow-up with short-sentences inmates

WHAT IS THE MODEL ABOUT?

Systematic HCV screening upon admission to prison and post-channel-release transition program to link inmates to specialist care after completing their sentence



Location

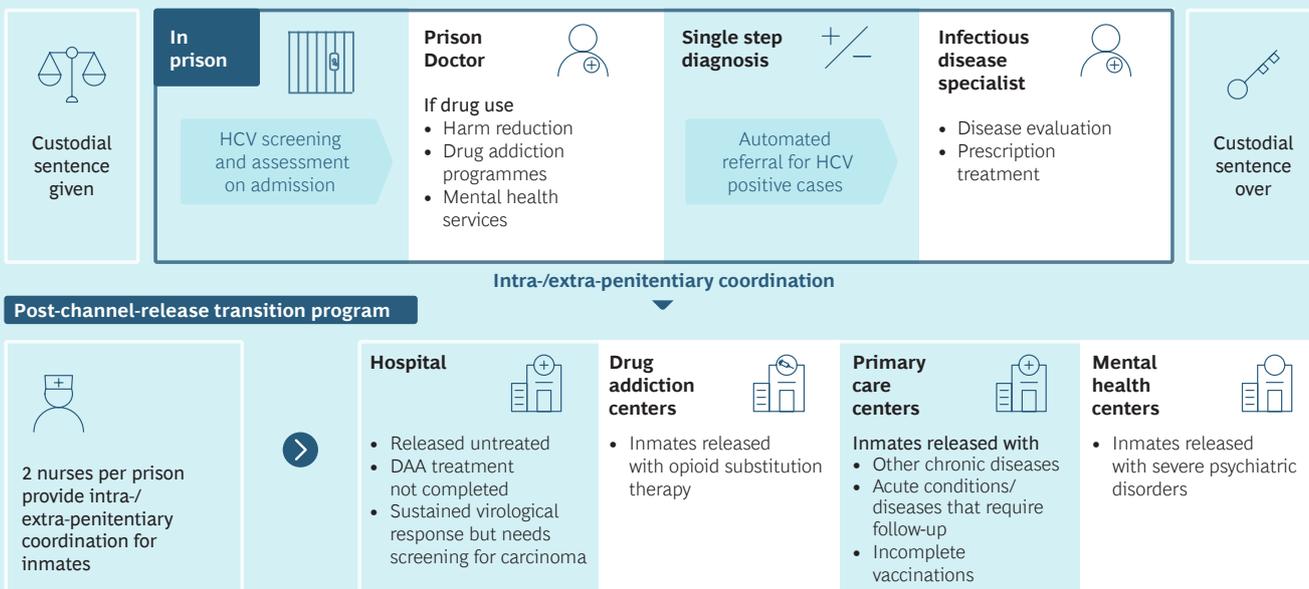
Prisons



Stakeholders

Primary care centres, hospitals, PWID channels, Ministry of Justice, Ministry of Health

HOW DOES IT WORK?



OUTCOME

Expected HCV elimination in the region's prisons by 2021

MAIN FIGURES DURING 2018-19

83.7%
of inmates screened

860
patients treated since 2015

2.2%
decrease in HCV RNA+



PILOT STUDY ON HIV PREVENTION PROGRAM FOR LATINO MSM

POPULATION AT RISK



MSM

LOCATION



Ontario, Canada

Authors: Jorge Luis Martínez-Cajas; Beatriz Alvarado; Barry D. Adam; Trevor Hart

PURPOSE



Reduce unprotected sex among the latino MSM community, the second most highly exposed racial group to HIV in the region

WHY IS THE MODEL NEEDED?

- Low psychological support to control addictive behaviors
- Limited information about sexually transmitted infections' (STIs) effects on health
- Insufficient medical staff to support these patients along the care process end-to-end
- Stigma about homosexuality and immigration
- Language and cultural differences with health providers

WHAT IS THE MODEL ABOUT?

Peer-based prevention model which provides information about STIs and emotional & psychological support



Location

Local community centers



Stakeholders

MSM community and HIV treatment clinics

HOW DOES IT WORK?

01

Training of local facilitators

- One peer selected from the community
- 35 hours of training on STIs and psychological support for patients



02

6 weekly 2-hour individual sessions led by a community peer, covering:

- HIV and other STIs' transmission
- Sexual behaviors and risks
- Means to improve sexual health
- Strategies for change and achieving personal goals

OUTCOME

Increased condom use in both HIV positive and HIV negative MSM

MAIN FIGURES OF THE PILOT

31%

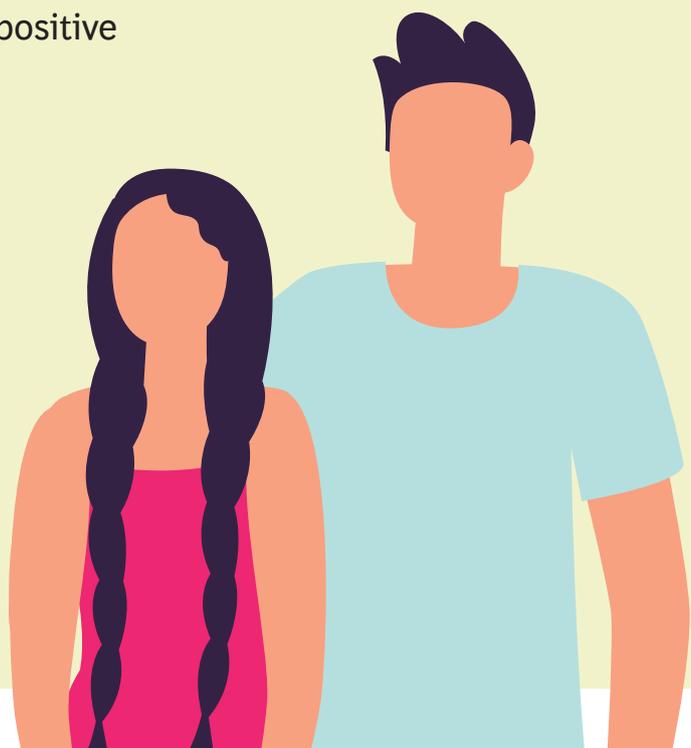
decrease of unprotected sex encounters during the following 3 months

46%

reduction of reported loneliness and sexual compulsivity behaviors

126

sessions provided



NO-MORE-C HCV-RNA HOME-BASED TESTING

POPULATION AT RISK



MSM

LOCATION



Amsterdam,
Netherlands

F. Zuure, U. Davidovich, T. Prinsenbergh, P. Zantkuijl, W. Zuilhof, M. Prins, M. van der Valk, J. Schinkel

PURPOSE



Reach MSM patients earlier by scaling-up screening and preventive measures

WHY IS THE MODEL NEEDED?

- Lack of information about HCV and how to prevent it
- Low psychological support to control addictive sexual behaviors
- False sense of protection (PrEP, serosorting, etc.)
- Stigma about homosexuality and taboo surrounding risky sexual behaviors
- Long process between screening and treatment

WHAT IS THE MODEL ABOUT?

Online and face-to-face interventions aimed to raise HCV awareness, promote risk reduction behavior and willingness to test



Location

Patients' home



Stakeholders

MSM community and HIV treatment clinics

HOW DOES IT WORK?



Website with information about HCV



Low-cost internet-guided home-based testing service



Free HCV prevention toolbox, containing items to help reduce risk for HCV-(re)infection

- 1 Risk assessment questionnaire used to self-assess HCV infection likelihood
- 2 Test is ordered through the website and sent to a chosen address
- 3 Self-collected HCV-RNA test using dried-bloodspots
- 4 Sample is sent by mail to a certified laboratory
- 5 Test results are communicated by login in at the website
- 6 Website guides users who test positive towards health care services for further evaluation

OUTCOME

Increased HCV awareness by allowing men to test anonymously at home

MAIN FIGURES DURING FEB'18-SEP'19

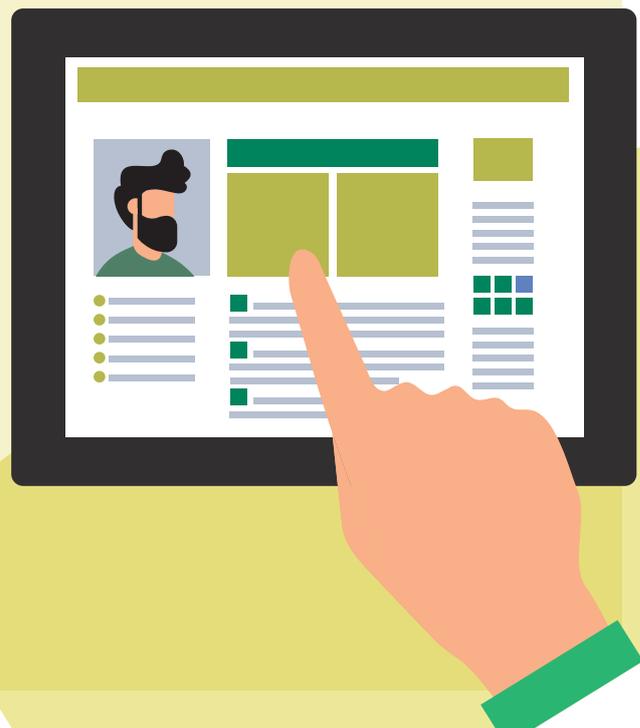
26,500 users visited the page

1,609 users accessed the advice tool

678 were advised to test

9% ordered the test

6% of samples tested positive



COMMUNITY-BASED INTEGRATED SCREENING FOR HCV, HBV, HIV AND SYPHILIS

POPULATION AT RISK



MSM

LOCATION



Portugal

Authors: D. Simões, R. Freitas, M. Rocha, P. Meireles, A. Aguilar, H. Barros

PURPOSE

Improve screening processes to raise diagnosis rates for multiple diseases



WHY IS THE MODEL NEEDED?

- Fragmented health system structure
- Lack of awareness of HCV's health effects
- Different campaigns for diseases with the same target segments
- Limited epidemiological data to improve screening campaigns' effectivity
- Limited HCV education programs for care providers

WHAT IS THE MODEL ABOUT?

Integrated strategy for different blood-borne viruses to optimize testing opportunities with current care structure



Location

Local care centers for HIV treatment and other community facilities



Stakeholders

80 professionals
28 screening points
18 organizations

HOW DOES IT WORK?

01

Train organizations' staff, medical and non-medical, to provide rapid screening tests for multiple infectious diseases

02

Offer a questionnaire to patients to understand better their specific situation, follow up their case and obtain epidemiological data

03

Escort infected patients from the organizations to the referred specialist in the hospital

04

Analyze data, at a national and local level, using common indicators to measure the effectivity of testing campaigns

05

Understand infection patterns (e.g. coinfections, segments' size, virus outbreaks, etc.) to develop new initiatives

OUTCOME: THE COMMUNITY SCREENING MODEL DURING 2016

Increased disease awareness among individuals living with HCV in non-hospital settings by integrating multiple tests

35,494

tests provided

5,931

individuals screened

827

infections detected



INTEGRATED APPROACH TO HCV SERVICES FOR REFUGEES IN RURAL AREAS

POPULATION AT RISK



Migrants

LOCATION



Victoria, Australia

Authors: Watkinson S, Higgins L, Sasadeusz J, Biggs BA, Cowie BC, Schulz TR



PURPOSE

Establish a community-based clinical service pilot for refugees to improve their access to HCV treatment

WHY IS THE MODEL NEEDED?

- Mistrust towards institutions (e.g., fear of being deported)
- Lack of testing sites at newcomer health services
- Challenge to complete pathway (e.g., nomadic behaviors)
- Poor medical facilities within internment centers
- Not included in health systems and therefore no access to treatment

WHAT IS THE MODEL ABOUT?

Coordinated action against HCV to reach migrants through community channels



Location

Community viral hepatitis clinics supported by telemedicine services



Stakeholders

Primary care centers, immigration authorities, Ministry of Health



Community care

Local care by PCPs in the community clinics, enabled by portable FibroScan®
Telemedicine consultations when onsite visit was not possible or to contact specialists
Local dispensing from regional pharmacies



Care coordination

Assigned a nurse to follow the patient's progress and coordinate with specialist and PCP
Partnership with community partners to provide complementary services including psychology, trauma counseling, etc.
Interpreting services when requested by the client



Information support

2-4 weekly support phone calls to monitor treatment compliance and side effects
Printed copies of the treatment management plan
Specialists were available at any time to provide advice if needed

OUTCOME

Established a successful model of care to manage a culturally and linguistically diverse group

MAIN FIGURES OF THE PILOT

14
patients started treatment

88%
reached treatment completion



ARRIVAL CARE SERVICES FOR REFUGEES

Authors: T. Prestileo, V. di Marco, O. Dino, A. Sanfilippo, F. di Lorenzo, M. Tutone, M. Milesi, C. Picchio, A. Craxi, J.V. Lazarus

POPULATION AT RISK



Migrants

LOCATION



Sicily, Italy

PURPOSE

Provide care earlier to HCV-endemic-regions migrants to treat those infected as soon as they enter the country



WHY IS THE MODEL NEEDED?

- No access to free HCV treatment for those undocumented or asylum seekers who are not included in the national health systems
- Lack of resources to test for HCV
- Nomadic behaviors
- Language and cultural differences with health providers

WHAT IS THE MODEL ABOUT?

Grant screening for HCV, HBV and HIV, linkage to care and treatment for refugees at country arrival



Location

Migrant internment centers



Stakeholders

41 regional care centers

HOW DOES IT WORK?



Blood-borne virus screening within 6 weeks after arrival



Liver evaluation if HCV or HBV positive
HBV vaccination if negative



Treatment access for those infected

OUTCOME

Provided early and effective care for migrants

MAIN FIGURES 2015-17

2,751 migrants offered screening

96% accepted to be screened

145 cases identified

88% started treatment



VIRAL HEPATITIS SCREENING FOR FOREIGN-BORN LEGAL MIGRANTS

POPULATION AT RISK



Migrants

LOCATION



Grampian, Scotland

Authors: Maria K Rossi, Rachel Thomson, Laura Kluzniak, Irene K Veldhuijzen



PURPOSE

Develop viral hepatitis screening strategies for migrants in community settings

WHY IS THE MODEL NEEDED?

- Low awareness of HCV endemic regions among frontline workers and primary care providers
- Language and cultural differences with health providers
- Heterogeneous group with diverse backgrounds
- Stigma associated to their HCV and foreigner condition
- Limited contact with the local healthcare system

WHAT IS THE MODEL ABOUT?

Pilot screening model for viral hepatitis among migrant populations



Location

Universities and workplaces



Resources

Nurses
Phlebotomists
Interpreters

HOW DOES IT WORK?

01

Awareness-raising for target population with posters and briefing sessions

02

Risk exposure questionnaire

03

Hepatitis test and sample sent to laboratory

04

Results communication to patient, translated by an interpreter

Positive, by telephone
Negative, by post

05

Referral to specialist

OUTCOME

Demonstrated effectivity of screening migrants for viral hepatitis at university and workplace settings

MAIN FIGURES OF THE CAMPAIGN

100

screening hours

461

people screened

13

infections identified



C-FREE-SOUTH MULTI-LEVEL INTERVENTION MODEL TO ELIMINATE HCV

POPULATION AT RISK



Birth cohorts / Other groups

LOCATION



Southern Denmark Region

Authors: Peer Brehm Christensen and Anne Øvrehus

PURPOSE

Eliminate HCV in the region through an at-risk population approach

WHY IS THE MODEL NEEDED?

- Limited public awareness of HCV
- Low political commitment
- Stigma, associating the virus with drug use
- Lack of resources to conduct screening campaigns
- Limited knowledge about testing strategies' cost-effectiveness

WHAT IS THE MODEL ABOUT?

Micro-elimination strategy which targets elimination for the main populations at risk



Location

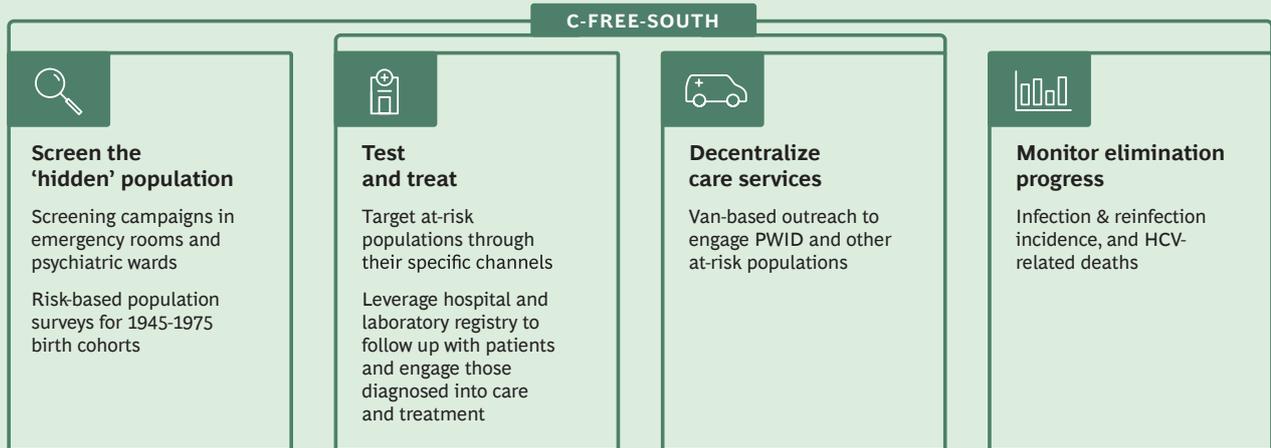
Hospitals, primary care centers and other community facilities



Stakeholders

Regional health services, community organizations, Ministry of Health, and politicians

HOW DOES IT WORK?



OUTCOME: THE C-FREE-SOUTH MODEL BY 2025

Expected to achieve HCV elimination in the region by 2025

44%
of infected expected to be diagnosed

64%
of patients to be provided treatment



2019 TOUR DE FRANCE HCV AWARENESS CAMPAIGN

POPULATION AT RISK



Birth cohorts /
Other groups

LOCATION



France



PURPOSE

Raise awareness among general population on the relevance of getting screened for HCV

WHY IS THE MODEL NEEDED?

- Large investment generally needed to increase impact of awareness campaign
- Patients are difficult to reach due to diverse lifestyles

WHAT IS THE MODEL ABOUT?

Comprehensive media campaign built around 3 key messages and a unique call to action to encourage people to get tested



Campaign messages

75,000 people are unaware that they have hepatitis C
Hepatitis C affects everyone
Nowadays, hepatitis C can be cured



Location

- 1 Special Tour de France deployment
- 2 TV, websites and social networks

HOW DOES IT WORK?



Awareness raising

2 noise-making vans following cyclists, distributing goodie bags, and engaging visitors in on-site prevention & screening activities



Screening campaign

Rapid-diagnosis tests located in every village departure and arrival, and fan parks



Media coverage

Key messages and photos shared on social media, TV & radio

OUTCOME

Maximized exposure of audience to campaign messages, encouraging on-site screening

MAIN FIGURES

600

rapid-diagnosis tests

180K

goodies distributed to spread awareness & prevention messages

9.7M

people exposed to awareness-raising and prevention messages via social media

212M

global audience reached via TV & radio

Source: Press articles; www.addiction-agency.com



FOCUS GALICIA PILOT PROGRAM TO IDENTIFY PATIENTS TO BE TESTED FOR HCV AND HIV

POPULATION AT RISK



Birth cohorts /
Other groups

LOCATION



Pontevedra and O Salnés,
Spain



PURPOSE
Leverage age and patients medical history to identify patients who should be tested for HCV and HIV

WHY IS THE MODEL NEEDED?
Challenge to identify patients to screen in general population

WHAT IS THE MODEL ABOUT?

Leverage artificial intelligence software to select patients who should be screened for HCV and HIV, and accelerate referral to specialist and linkage to care



Location

Hospitals and primary care facilities

HOW DOES IT WORK?



Software filters all patients who visit a primary care facility for any reason
Selects those who are between 20 and 70 years old and who according to their medical history have not been tested for HCV or HIV in the past



PCP is notified in real time by the system to schedule serology analyses for those selected patients



Follow-up is guaranteed for all positive cases, with patients being evaluated quickly and referred to the due specialist



In less than 7 days, patients can initiate treatment

OUTCOME

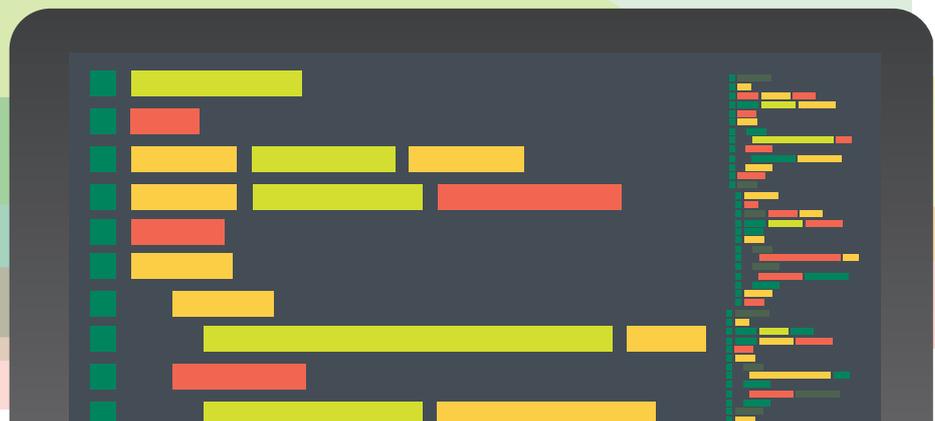
Found patients who were unaware of their HCV or HIV condition, improving their quality of life and achieving savings for the health system

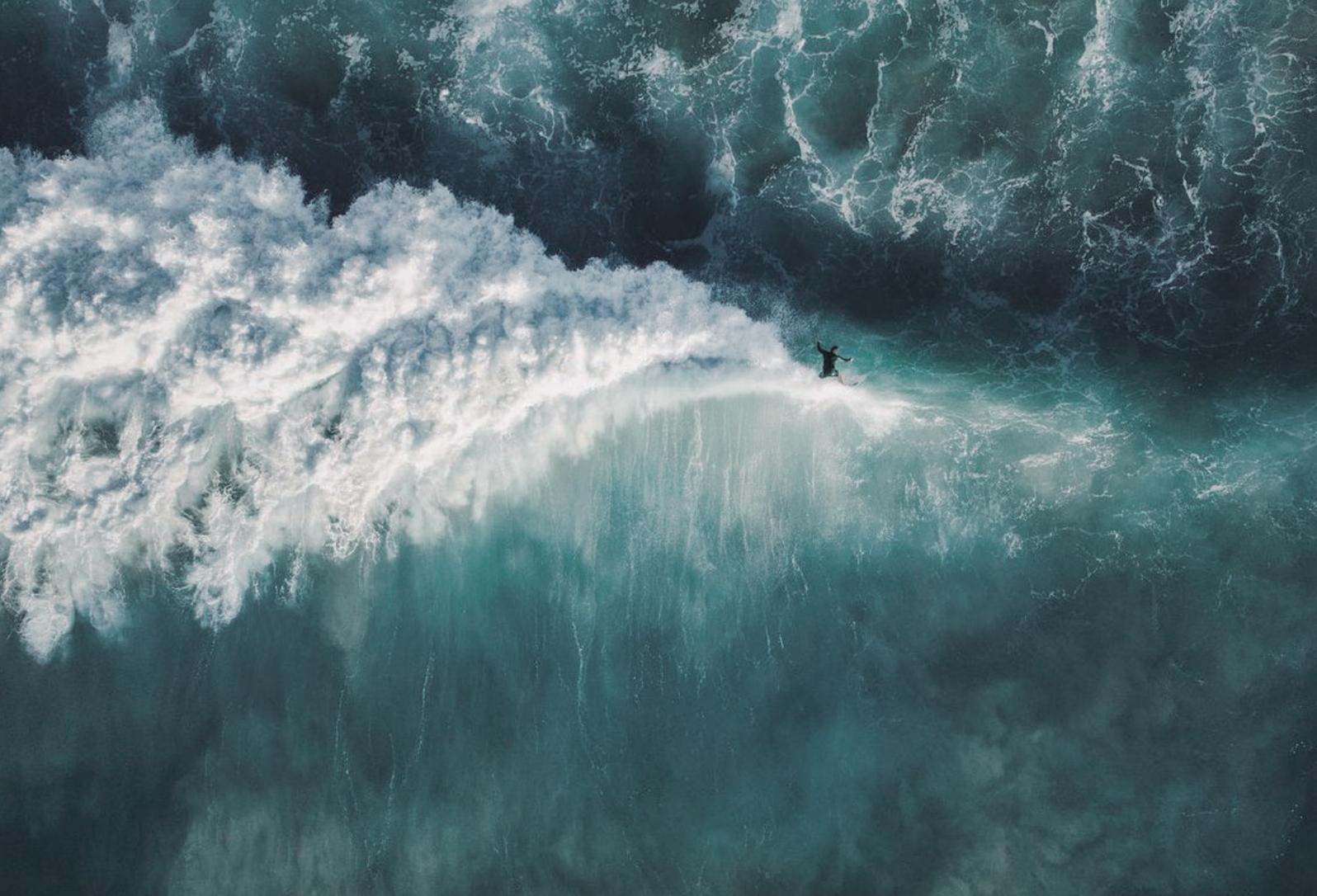
MAIN ESTIMATED FIGURES FOR THE FIRST YEAR

~200
HCV-positive patients detected

~50
HIV-positive patients identified

Source: Press articles





Call to action

Innovative treatment developments and highly effective prevention measures have made achieving HCV elimination during this decade possible. If countries follow the WHO recommendations set out to achieve the UN Sustainable Development Goals, which include combatting viral hepatitis, a scenario where HCV is eliminated can become a reality. This historic moment will require policymakers' strong commitment to prioritizing and investing resources in HCV. This will **improve people's lives**, not only in terms of their health but also by eliminating the stigma and discrimination. Moreover, it may potentially bring significant **cost-savings to the health system in the long term**. Lastly, there is a **reputational recognition** for elimination leaders, positioning them as role models in the global health scene.

In those countries where health authorities are not taking action and there is a lack of reliable epidemiological data, other stakeholders (e.g. the scientific community, hospital management) must step up and develop micro-elimination strategies.

As disease complications are expected to increase rapidly with an aging population, governments and health ministries must step up their elimination efforts and leverage treatment affordability to improve HCV diagnosis and treatment in order to realize elimination by 2030.

In sum, the main actions that should be considered by all countries to reach the WHO HCV elimination goal are:

1. **Develop solid, national elimination plans** with defined country-specific targets and strategic actions to use resources efficiently.
2. **Allocate resources to HCV elimination strategies and establish new funding mechanisms to make treatment more accessible** through price/volume discounts or more innovative pricing schemes, such as the flat-fee model implemented in Australia, to offset the cost of treatment.
3. **Implement comprehensive HCV screening policies** to identify the undiagnosed. In order to make them cost-effective, adapt campaigns to the country's disease epidemiology.
4. **Decentralize test and treat programs** to reduce drop-out rates and ensure all diagnosed individuals are treated.
5. **Extend harm reduction programs** to prevent new cases, as injecting drugs is the main source of new infections in high-income countries (>80%)⁵³.
6. **Measure HCV through a standardized prevalence database and define outcomes-based targets** across all countries to evaluate their performance

against the WHO targets on a yearly basis and **with reliable data**. Robust, accessible and useful indicators should be collected at country level and subsequently monitored by an international organization, such as the WHO and relevant regional bodies, that provides oversight of the progress of HCV elimination¹³¹. At the national level, this is essential to understand the local characteristics of the disease, improve national plans, and create micro-elimination strategies. This will allow for the identification and treatment of more patients at earlier stages of the disease.

Looking ahead, the country experts that contributed to this report still consider HCV elimination an achievable goal for 2030, provided that sufficient investment is made in covering the testing and treatment costs, decentralizing testing, and hiring and educating healthcare staff. **HCV elimination by 2030 will only be possible if real action is taken now.**

⁵³ The World Health Organization (2016). Monitoring and Evaluation for viral Hepatitis B and C: Recommended indicators and framework.



Further information

Overall approach

This report assesses the current status of HCV elimination of **29 countries**, covering Europe, Australia, and Canada. The aim is to determine the progress made in elimination in the last three years, an analysis of the **main barriers and critical success factors** to achieving elimination, and a forward-looking **people-centered approach**. The report looks into primary at-risk groups affected by HCV, their distinct needs, and how to improve their treatment rates, in addition to highlighting how to reach the remaining smaller populations at risk. Moreover, the report includes a **models-of-care perspective** and shows how this can help healthcare authorities implement effective strategies to battle HCV.

BCG Managing Directors and Partners María López and Paulo Gonçalves, and Consultant Teresa Ko have held editorial control of the report throughout. A scorecard was created summarizing the status of the countries covered by the report in terms of key metrics based on the progress of national plans, monitoring, and tracking of patients. The scorecard was developed by BCG analysts with the support and validation of experts and clinicians from the countries in scope.

The report includes an overall assessment of the barriers and critical success factors identified today in the care cascade. Additionally, for each of the groups reviewed, a profile was developed using input from the available literature, followed by validation interviews and the review of an Advisory Committee. Common sources of information were national plans, scientific papers, previous reports on HCV, and the media.

When country examples are mentioned in the report, they reflect the overall perception in the country, but may not apply to all regions within it. Moreover, research study results are difficult to compare given the heterogeneity of definitions across countries. This is compounded by the fact that large-scale studies capable of ensuring the reliability of epidemiological data and quantifying the size of the different at-risk groups with enough certainty are often lacking in the current literature, since many governments are not monitoring the progress of HCV elimination.

Analyses conducted

Over 20 experts from the different countries within the report's scope, including clinicians, academics, regulators, payers, scientists, and patient association representatives, were interviewed or provided information to complete and validate each group's profile. Interviews usually lasted forty-five minutes, were preceded by a brief questionnaire template, with questions covering the information needed to obtain an in-depth analysis of the target groups,

taking into account the expertise of the interviewee. However, the opinions expressed may not always reflect the opinion of the organizations to which the experts belong. All interviewees agreed to participate on a pro-bono basis, and while some wish to remain anonymous, we have taken the opportunity to acknowledge the contribution of others:

- Soo Aleman – MD, PhD, Associate Professor and Head of HIV, Viral hepatitis and Immunodeficiency disorders units, Department of Infectious Diseases at Karolinska University Hospital/Karolinska Institute, Stockholm, Sweden
- Dr. Iain Brew – National Deputy Medical Director for Health in Justice, England
- Dr. Yuval Dadon – MD, MBA, Lead of Health Ministry's National HCV Elimination Plan, Israel
- Prof. Victor de Ledinghen – Hepatology at the University Hospital of Bordeaux, Member of the European and American Associations for the Study of the Liver, and Secretary of the French Association for the Study of the Liver, France
- Jesús María Fernández – Former Deputy Spokesman of the Health and Social Services Commission, Spain
- Graham Foster – Professor of Hepatology at Queen Mary University and the clinical lead for hepatology at Barts Health, former President of The British Viral Hepatitis Group and former President of the British Association for the Study of The Liver, England
- Mark Gillyon-Powell JP – Head of Programme HCV Elimination, NHS England and NHS Improvement, Specialised Commissioning, England
- Prof. Angelos Hatazakis – MD, PhD, MSc, Epidemiology & Preventive Medicine and Director of the Department of Hygiene, Epidemiology & Medical Statistics at Athens University Medical School, Greece

- Sari Högström – Executive Director, Liver and Kidney Patient Association, Finland
- George Kalamitsis – Chair of Board of the Liver Patient Association “Prometheus”, Greece
- Daniel Lavanchy – MD, Consultant and former Coordinator & Chief of Viral Diseases for the WHO, Switzerland
- Daryl Luster – President of the Pacific Hepatitis C Network (PHCN) and Executive Member of the Steering Committee of Action Hepatitis, Canada
- Felice Nava – Director of the Penitentiary Medicine and Drug Abuse Unit part of the Public Health Service, Padua, Italy
- Dr. Juha Oksanen – Micro-elimination of Hepatitis C, Kotka Opioid Substitution Therapy Clinic, Finland
- Anne Øvrehus – MD, PhD, Consultant and Clinical Associate Professor, Department of Infectious Diseases, Odense University Hospital, Denmark
- Prof. George Papatheodoridis – MD, PhD, Director of Academic Department of Gastroenterology, Athens University Medical School, Greece
- David Pešek – Head of Sananim, NGO operating in the area of PWID care, Czech Republic
- Dr. Nazifa Qurishi – Specialist in internal medicine and infectious diseases, Cologne, Germany
- Swiss Hepatitis C Association (SHCA), Switzerland
- Dr. Juan Turnes – PhD, Head of Gastroenterology and Hepatology Department, University Hospital of Pontevedra, Spain
- Helen Tyrrell – Former Chief Executive Officer, Hepatitis Australia
- Dr. Wim Verlinden – Specialist in gastroenterology and hepatology at AZ Nikolaas Hospital, Belgium
- Dr. Jindrich Voboril – Head of Podane Ruce, NGO operating in the area of PWID care, Czech Republic

The report was developed in collaboration with an Advisory Committee, which consisted of three members known for their expertise in HCV elimination, and was formed to oversee the report and its recommendations. The members are:

- Jeffrey V. Lazarus - Associate Research Professor at the Barcelona Institute for Global Health (ISGlobal), also a member of the Expert Review Panel from the previous report
- Cary James - CEO of the World Hepatitis Alliance
- Dr. Andrew Ustianowski - Clinical lead for the Greater Manchester HCV Elimination Programme and former chair of the British Viral Hepatitis Group

About the Authors

Paulo Gonçalves is a Managing Director and Partner in the Barcelona office of Boston Consulting Group

María López is a Managing Director and Partner in the Madrid office of Boston Consulting Group

Teresa Ko is a Consultant in the Madrid office of Boston Consulting Group

Selected criteria for country scorecard

For each of the dimensions considered in the HCV status scorecard, a series of criteria were defined to ensure consistency in the evaluation of each country. The scorecard assesses the situation of countries on April 2020.

Strategic plan in place	<p>Yes</p> <p>The government has published a publicly available national plan as a guide to achieving HCV elimination.</p>	<p>No</p> <p>There is no publicly available national HCV plan.</p>			
Achieving HCV elimination by 2030 objective in plan	<p>Yes</p> <p>The national plan sets the year 2030 (or before) as target year in which the country aims to achieve elimination based on their estimates.</p>	<p>No</p> <p>There is no national plan, or if there is, it does not mention a target year to reach HCV elimination.</p>			
Monitoring of impact of each of the initiatives	<p>Yes</p> <p>Initiative results are closely monitored through pre-defined milestones and indicators.</p>	<p>Partially addressed</p> <p>Although overall progress of the initiatives is being followed, there are no specific delivery dates or the indicators are too generic and therefore it is hard to measure real progress.</p>	<p>Planned</p> <p>Initiative progress is expected to be followed in the near future, but the specific indicators to be monitored have not been decided yet or the monitoring infrastructure is still not in place.</p>	<p>Not addressed</p> <p>The government does not periodically review the progress made in initiatives that aim to achieve elimination.</p>	<p>No plan</p> <p>There is no national HCV plan with initiatives to be monitored.</p>
HCV national patient registry	<p>Well addressed</p> <p>There is an organized national database where patient profiles from across the country are recorded consistently. Depending on the country, the scope may vary: from recording all new cases, only those under treatment, etc.</p>	<p>Not addressed</p> <p>There is no type of patient registry or it does not have a national scale, such as clinical research trials or regional databases.</p>			

Abbreviations

AASLD: American Association for the Study of the Liver
ALEH: Latin-American Association for the Study of the Liver
APASL: Asian Pacific Association for the Study of the Liver
APRI: AST to Platelet Ratio Index
CEO: Chief executive officer
CDC: Center for Disease Control and Prevention
DAA: Direct-acting antivirals
EASL: European Association for the Study of the Liver
ECDC: European Center for Disease Control and Prevention
EMCDDA: European Monitoring Centre for Drugs and Drug Addiction
EU/EEA: European Union (EU) and European Economic Area (EEA)
HBV: Hepatitis B virus
HCV: Hepatitis C virus
HIV: Human immunodeficiency virus
MSM: Men who have sex with men
NGO: Non-governmental organization
OST: Opioid substitution therapy
PCP: Primary Care Practitioner
PHCN: Pacific Hepatitis C Network
PrEP: Pre-exposure prophylaxis
PWID: People who inject drugs
RNA: Ribonucleic acid
SHCA: Swiss Hepatitis C Association
STI: Sexually transmitted infections
UK: United Kingdom
UN: United Nations
US: United States of America
WHA: World Hepatitis Alliance
WHO: World Health Organization



BCG

2020